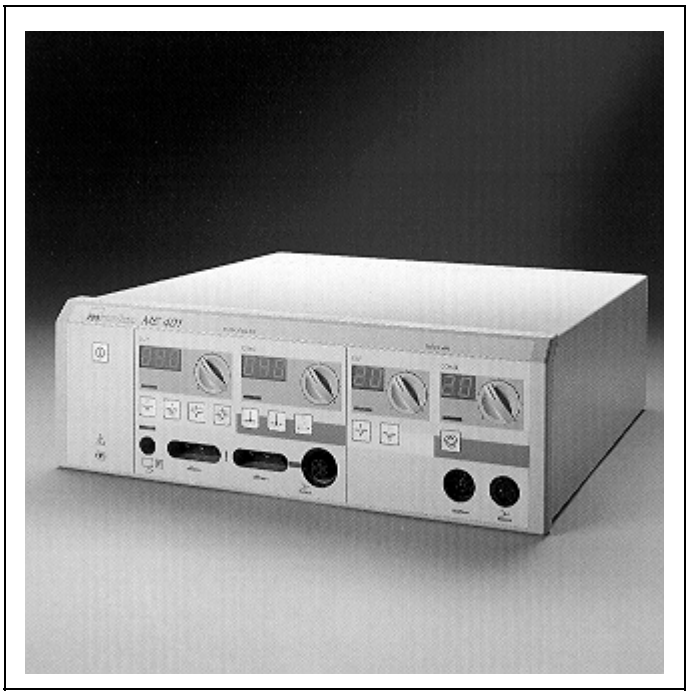

Martin ME 401

Service Manual

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SERVICE MANUAL ME 401 Rev.2.1

This documentation is made to give to the service people all information to enable them to detect and remove disturbances and defects at the electrosurgery unit ME 401 and to verify the operating data and the functional safety.

Herein included is a technical description of the unit, an assembling instruction for the exchange of modules, an instruction for finding out certain faults by a formal procedure, alignment instructions and presentation of the design revisions established in the course of time. The knowledge of the user's instruction manual will be presupposed.

In the foot line of this document is indicated:

- Author Martin Medizin-Technik, responsible for contence
- Editor
- Validity for electrosurgical unit ME 401
- State of revision
- Page number

The state of revision is indicated in the form X.Y. In case of editorial corrections or supplements, the digit Y will be advanced for 1. In the case of general alterations or novelties with the unit, the digit X will be advanced for 1 and the digit Y will be reset to zero. Thus the former release of the service manual looses validity for all new releases of the unit.

Alterations and supplements with respect to version 2.0 are in italic letters.

1. Technical Description of the ME 401

1.1 General

The MARTIN ME 401 was designed as an universal electrosurgical unit for clinical use and incorporates in relation to its predecessors the following alterations, improvements and supplements:

- Internal control by microcontroller
- Setpoint indication corresponding to estimated electrical output power
- Bipolar cutting
- RF output power control by characteristic field control
- Redesigned more ergonomic layout of the front panel
- New output sockets with stepdown compatibility for former accessories
- Omission of the MICRO-Key, but now progressive setting of RF power
- Omission of the selection keys for finger/foot switch control
- Selection key for automatic stop of bipolar coagulation, optional automatic start of bipolar coagulation (from hardware version 04 upwards)
- Adaptive neutral electrode monitoring with circuit fault detection
- Improved spray coagulation by enhanced output voltage
- Power-on self test and detailed error messages
- Monitoring and active limitation of RF leakage currents
- More easy manufacture and more easy service by screwless board assembly
- Two special monopolar cutting current modes for cutting under liquid
- Ability of bipolar instrument identification

Maintained is the concept of two separated generators for monopolar and bipolar RF with the ability of simultaneous activation, the access to all connectors and setting means except the mains connection at the front, the power setting with rotary knobs for each operation mode and the current and operating mode selection by lighted keys.

1.2 Technical Data

1.2.1 Versions 0103, 0303, 0204, 0304 (serial end numbers 0010 to 0384)

Mains voltage:	100V/115V/127V/130V/240V 50-60Hz, to be set by change of soldered jumpers	
Input Power:	Approx. 1VA in the switch-off state, 42VA without RF activation, 880VA at maximum output power of both generators	
Output power:	Monop. Cutting 1:	max. 320W at 500 Ohms
	Monop. Cutting 2a:	max. 320W at 500 Ohms
	Monop. Cutting 2b:	max. 320W at 600 Ohms
	Urolog. Cutting 1:	max. 320W at 700 Ohms
	Urolog. Cutting 2:	max. 320W at 800 Ohms
	Contact Coag. 1:	max. 250W at 500 Ohms
	Contact Coag. 2:	max. 250W at 500 Ohms
	Spray Coagulation:	max. 100W at 1500 Ohms
	Bipolar Cutting 1:	max. 80W at 600 Ohms
	Bipolar Cutting 2:	max. 80W at 600 Ohms
	Bip. Coagulation:	max. 80W at 100 Ohms
Crest factors:	Monop. Cutting 1:	1.8 at 320W at 500 Ohms
	Monop. Cutting 2a:	2.2 at 320W at 500 Ohms
	Monop. Cutting 2b:	2.3 at 320W at 600 Ohms
	Urolog. Cutting 1:	1.8 at 320W at 700 Ohms
	Urolog. Cutting 2:	2.3 at 320W at 800 Ohms
	Contact Coag. 1:	1.8 at 250W at 500 Ohms
	Contact Coag. 2:	2.4 at 250W at 500 Ohms
	Spray Coagulation:	5.1 at 100W at 1500 Ohms
	Bipolar Cutting 1:	1.8 at 80W at 600 Ohms
	Bipolar Cutting 2:	2.1 at 80W at 600 Ohms
	Bip. Coagulation:	1.8 at 80W at 100 Ohms
Output voltages:	Monop. Cutting 1:	max. 2000VPP, open circuit
	Monop. Cutting 2a:	max. 2600VPP, open circuit
	Monop. Cutting 2b:	max. 3200VPP, open circuit
	Urolog. Cutting 1:	max. 2200VPP, open circuit
	Urolog. Cutting 2:	max. 4000VPP, open circuit
	Contact Coag. 1:	max. 1800VPP, open circuit
	Contact Coag. 2:	max. 2700VPP, open circuit
	Spray Coagulation:	max. 6500VPP, open circuit
	Bipolar Cutting 1:	max. 1200VPP, open circuit
	Bipolar Cutting 2:	max. 1400VPP, open circuit
	Bip. Coagulation:	max. 450VPP, open circuit
Protection class:	I	
Patient circuit:	CF defibrillation proof, monopolar and bipolar	
Operation mode:	INT 10s/30s	
Dimensions:	405mm X 135mm X 380mm	
weight:	13.6kg	

1.2.2 Versions 0406, 0506, 0606, 0706, 0807 and 0810 (from serial end number 0385)

Mains voltage:	100V/115V/127V/130V/240V 50-60Hz, to be set by change of soldered jumpers	
Input Power:	Approx. 1VA in the switch-off state, 42VA without RF activation, 880VA at maximum output power of both generators	
Output power:	Monop. Cutting 1:	max. 320W at 350 Ohms
	Monop. Cutting 2a:	max. 320W at 350 Ohms
	Monop. Cutting 2b:	max. 320W at 800 Ohms
	Urolog. Cutting 1:	max. 320W at 350 Ohms
	Urolog. Cutting 2:	max. 320W at 800 Ohms
	Contact Coag. 1:	max. 250W at 100 Ohms
	Contact Coag. 2:	max. 150W at 500 Ohms
	Spray Coagulation:	max. 100W at 1000 Ohms
	Bipolar Cutting 1:	max. 80W at 500 Ohms
	Bipolar Cutting 2:	max. 80W at 500 Ohms
	Bip. Coagulation:	max. 80W at 100 Ohms
Crest factors:	Monop. Cutting 1:	1.8 at 320W at 350 Ohms
	Monop. Cutting 2a:	2.2 at 320W at 350 Ohms
	Monop. Cutting 2b:	2.3 at 320W at 800 Ohms
	Urolog. Cutting 1:	1.8 at 320W at 350 Ohms
	Urolog. Cutting 2:	2.3 at 320W at 800 Ohms
	Contact Coag. 1:	1.8 at 250W at 100 Ohms
	Contact Coag. 2:	2.4 at 150W at 500 Ohms
	Spray Coagulation:	5.1 at 100W at 1000 Ohms
	Bipolar Cutting 1:	1.8 at 80W at 500 Ohms
	Bipolar Cutting 2:	2.1 at 80W at 500 Ohms
	Bip. Coagulation:	1.8 at 80W at 100 Ohms
Output voltages:	Monop. Cutting 1:	max. 2100VPP, open circuit
	Monop. Cutting 2a:	max. 2700VPP, open circuit
	Monop. Cutting 2b:	max. 3300VPP, open circuit
	Urolog. Cutting 1:	max. 2100VPP, open circuit
	Urolog. Cutting 2:	max. 4100VPP, open circuit
	Contact Coag. 1:	max. 1300VPP, open circuit
	Contact Coag. 2:	max. 3600VPP, open circuit
	Spray Coagulation:	max. 6500VPP, open circuit
	Bipolar Cutting 1:	max. 800VPP, open circuit
	Bipolar Cutting 2:	max. 1100VPP, open circuit
	Bip. Coagulation:	max. 420VPP, open circuit
Protection class:	I	
Patient circuit:	CF defibrillation proof, monopolar and bipolar	
Operation mode:	INT 10s/30s	
Dimensions:	405mm X 135mm X 380mm	
weight:	13.6kg	
CE 0123	conform with 93/42/EEC	

1.3 Features and Operation

The front panel of the ME 401 is designed in a manner that the relationship to the predecessing units is clearly visible, but the layout is impoved with respect to clearness and self-explanation of functions. Coherent functions are arranged in separated blocks, some functions which were isolated at the predecessing units are now combined.

The ME 401 has two monopolar and two bipolar operating modes, whereat one monopolar and one bipolar operation mode can be activated simultaneous. There is an own power setting for each operation mode.

Power setting is performed by rotary knobs. The set power rises not linear with the angle of turn, but approximately exponential. This makes that a change in setting for one unit does not mean a change in output power of 30 Watts, but a change of 10 percent of the actual value (progressive setting characteristic). This is an ergonomic more meaningful way of power setting characteristic. Because this enables the power to be set precisely even in the lower range, the MICRO function known from the predecessing units is obsolete.

The set power is displayed with a green LED display as a prospective electric output power for each mode of operation. Starting from 8 Watts at the monopolar cutting current modes, 5 Watts at the spray coagulation, 8 Watts at the monopolar contact coagulations and 4 Watts at the bipolar operation modes, the power increases first in steps of 1 Watt which increase with increasing angle of turn. The range of turn which appears to be continuous is divided in 64 fixed steps.

The selection of a current mode of an operation mode is performed by mutual releasing lighted keys. The selection of one current will be acknowledged by illumination of the pushed key. The ME 401 offers five monopolar cutting current modes, three monopolar coagulation current modes, two bipolar cutting current modes and one bipolar coagulation current mode. The first monopolar cutting current mode "Monopolar Cutting 1" is provided for smooth, i. e. as few as possible eschar forming cutting and will be selected by the first key. The second or third current mode "Monopolar Cutting 2" for eschar forming, i. e. hemostatic cutting will be selected by the second key. An internal switch enables the selection between two degrees of eschar formation, "Cutting 2a" and "Cutting 2b". The first two keys are equipped with the standard symbols for pure and eschar forming cutting.

The fourth monopolar cutting current mode "Urologic Cutting 1" is provided for smooth, the fifth "Urologic Cutting 2" for eschar forming cutting under liquid (e. g. transurethral resection). They are signed with modified symbols which correspond to them mentioned above.

The first and the fourth as well as the third and the fifth current mode do not differ in electrical RF power or course but only in their properties imposed by the control of field of characteristics which is new implemented in the ME 401. The power setting ranges from 8 Watts to 320 Watts for all five cutting current modes.

The "Contact Coagulation 1" will be selected by pushing the left key in the field of the operation mode monopolar coagulation. Power setting ranges from 8 Watts to 250 Watts.

The "Spray Coagulation" will be selected by pushing the right key with the standard symbol for this current mode. Due to an other process of RF current generation, the RF output voltage in this current mode is particulary high which enables a coagulation more confined to the tissue surface, clearly different from the contact coagulation which acts more in the depth. Power setting ranges from 5 Watts to 100 Watts.

The middle key (with the units of status 0103 or 0303, serial end numbers form 0010 to 0060, the left key in combination with one of the urologic cutting selection keys, blinking on selection,) selects "Contact Coagulation 2". This coagulation current is in its properties between that of the contact coagulation 1 and the spray coagulation. With respect to the predecessors, this function is new. With the units of status 0103, 00303, 0204 and 0304 (serial end numbers from 0010 to 0384), the power setting ranges from 8 Watts to 250 Watts, with the units of hardware status from 04 (from serial end number 0385), it ranges from 6 Watts to 150 Watts.

Bipolar cutting is also a new established operation mode which enables cutting with local restricted current especially in the field of endoscopic surgery in two current modes, "Bipolar Cutting 1" for smooth cut and "Bipolar Cutting 2" for eschar forming cut. Power setting ranges from 4 Watts to 80 Watts.

For bipolar coagulation, no current mode is to be selected because there is only this one. The illuminated key in this block is for activation and de-activation of the automatic bipolar stop function by repetitive keying (toggle mode). Operating a switch inside the unit (from hardware status 04 upwards, see item 4.3) enables additional automatic activation of bipolar coagulation. Lighting indicates the automatic mode to be active. Power setting ranges from 4 Watts to 80 Watts.

Activation of an operation mode will be indicated by a lamp in the corresponding front panel section and by an acoustic signal. After 15 seconds, the loudness of this signal raises. This time function can be disabled by a switch inside the unit. In the delivery state, this function is valid.

The monopolar sockets for the handpieces and the neutral electrode are recessed into the surface for improved safety against touchability of live parts.

The ME 401 offers an improved neutral electrode monitoring system which enables monitoring of single pad neutral electrodes for connection and cable damage as well as dual pad neutral electrodes additional for correct application. The monitoring of correct application is adaptive, i. e. the unit will tune automatically to the individual differences of electrodes of different manufacturers or patients. The effect that in one case the alarm will not disappear or only after long warmup time, in an other case alarm will not happen even though the electrode is half peeled off of the skin, will not occur anymore. The unit recognizes a sectioned single use electrode folded on itself or sticked to a metal surface as faulty (impedance alarm).

In the case of alarm due to not connected or insufficient applied neutral electrode, the red lamp above the neutral electrode connector socket will blink with half brightness. By the attempt of monopolar activation, the lamp will blink with full brightness and an intermitting acoustic signal appears. *From version 0406 (from serial end number 0385), the setting of a switch at the controller PCB makes the acoustic alarm appear not first on an attempt of activation but immediately. On delivery, this switch is reset.*

In the case of impedance alarm, this red lamp will blink with full brightness and half frequency so that this alarm state can be distinguished from the other one. This is important for the right trouble-shooting. In the alarm state, the monopolar RF current activation is disabled. The bipolar current activation is not concerned with this.

The option of connecting a single pad neutral electrode can be disabled by a switch inside the unit. Then, connecting of a single pad electrode results in impedance alarm. Where exclusively electrodes with splitted pads are used, this property can be used to monitor the correct short-free link of the cable clip to the single use electrode. In the delivery state, the unit is set to acceptance of single pad electrodes.

The ME 401 offers two identical monopolar active electrode sockets where a handpiece either with MARTIN coax plug or a three-pin plug as is common in the US market can be connected to. Both outputs can be activated by finger switches, the right output additional by foot switch. The activation functions are mutual locked in a manner that simultaneous operation of both finger switches or both foot switches or one finger switch and one foot switch related to the same output results in activation of none of both operation modes. A switch inside the unit determines whether the attempt of activation of both outputs simultaneously results in serving that output that tried activation first (paritetic control) or prefering the right output (hierarchical control). The last mentioned is the delivery state of the unit.

The monopolar foot switch socket is maintained unaltered.

For connection of bipolar accessories, a new socket was designed which enables connection of the yet existing accessories for bipolar coagulation with the hitherto cable plug (stepdown compatibility) as well as of the futural instruments with the ability of bipolar cutting. Additional, this socket enables the connection of bipolar accessories with finger switches for activation of both bipolar operation modes.

Furthermore, a recognition of connected accessory is provided. This offers for the first time the ability to give message about attributes like maximum permissible RF power, suggested activation time, suggested current mode etc. to the unit for optimum matching between generator and connected instrument. The unit identifies the instrument by a resistor inside the connector and can perform individual matching with the help of the EPROM tables. On introduction of new instruments an EPROM update is to be installed at the ME 401 to update the unit.

On pushing the key for automatic bipolar coagulation, an identification number appears in the bipolar coagulation power display. In case of an insrument with identification number which is installed at the unit, the identification number will be displayed. If the instrument has no identification, "00" will be displayed. In case of an identification which is not installed at the unit, "EE" will be displayed. Such an instrument will be treated like one without identification.

The ME 401 offers an automatic mode for bipolar coagulation which can be activated and disabled in toggle mode by the key with the "Automatic" symbol. On activation the key is illuminated. Otherwise than with the predecessors, in the setting as lelivered by the manufacturer the coagulation current will not be activated automatically on contact with tissue, but current stops when a certain degree of coagulation is gained. It must be activated by finger or foot switch. The ME 401 monitors the electric resistance between the coagulation electrodes. At the beginning of the coagulation process, this resistance decreases continuously and increases again in further course. As soon as the unit recognizes this, coagulation current will be disabled. In contrast to a monitoring of a fix value of resistance, this relative resistance monitoring offers the advantage of a coagulation result which is independent of electrode size and kind of tissue in a wide range.

In the delivery state, the ME 401 renounces an automatical activation of coagulation current on tissue contact of the electrodes, because in endoscopic surgery unintended tissue contact especially when the instrument is fed in or off the trocar cannot be excluded and an unintended activation by the automatic mode may result in undesired current activation with the possibility of uncontrolled necrosis. If automatic activation is explicite desired, the operation of an internal switch with units from hardware state 04 upwards (see item 4.3) enables automatic bipolar activation in the automatic mode. From this reason the automatic function is always set to off state when when mains power will be switched on.

The bipolar foot switch socket of the ME 401 is performed in a manner that the foot switch used for bipolar coagulation hitherto can be connected further, but only for activation of coagulation like before. Bipolar cutting needs a new double foot switch.

The mains connection with detachable cord together with the mains fuses and the circuit breaker is placed at the rear of the unit on the right side. Normally the circuit breaker is switched on, the unit will be set in the switched-on or in the standby mode by the key at the left side of the front panel. This is a real standby mode in which the mains power consumption is less than 1 Watt.

The mains voltage is already matched in manufacture, the setting is noted on the rear. A later change is possible by simple changing of soldered jumpers inside the unit. By change of mains transformer taps by soldering, the unit can be matched to the extraordinary voltages 100V (Japan), 127V (Mexico) and 240V (still in some areas of Great Britain).

On the rear there are in addition the equipotential connector, the outlet for the acoustic activation and alarm signal and a service alignment position for setting the required loudness.

The case is made from sheet steel with no venting slots. It stands on four pads.

For fixing to an underground, the unit has receptacles for pinning it up on ball bolts.

1.4 Mechanical Design

Guideline for the mechanical design was an almost simple and clear construction to make manufacture and service as easy as possible.

The case bottom serves as a chassis to pick up the printed circuit boards, the mains transformer, the mains terminal unit and the front panel with handling elements and sockets. The boards except the standby PCB are fixed in adhesive plastic bars at the bottom and in embossed beads (units of states 0103, 0303, 0204 and 0304, serial end numbers from 0010 to 0384) or between guiding pins (from hardware state 04 upwards, from serial end numbers 0385) at the sides without screws. From above, a comb shaped holder keeps the boards pressed down. Only the mains transformer because of its big mass and the standby PCB for safety reasons are mounted with screws which have to be loosened as usual.

The cable connections are radically simplified by confining all control lines to one bus cable, only the energy flow paths and the PE cables are performed as single lines, the most of them connected fix at one end. This is visible from the wiring diagram.

The front part is placed in guiding grooves at the bottom and only fixed and arrested in its position by two threaded bolts. At this front part, the sockets are mounted directly or by means of plates, the front PCB will be held by a screwless snap-in fixing. At the front the top cover will be held in a groove in the front panel, at the rear with four screws at the rim.

The unit consists of the following components in which it can be dismantled for service or demonstration purposes:

- Case bottom with board holders, stands and type plate
- Top cover
- Mains terminal unit with mains fuses and circuit braker
- Top holder for PCBs
- Handle with reversal cover
- Equipotential connection pin with insulation
- Subassembly with sound transducer and setting for loudness
- Grounding cables for PE, potential equalization and ground potential
- Bus cable
- Standby circuit cable
- Mains transformer
- Standby PCB
- Controller PCB with auxiliar supply and sound generator
- Bipolar RF generator PCB
- Monopolar RF generator PCB
- RF output PCB with setpoint generation and monitoring

- Front panel, consisting of sub-components as follows:

  - Plastic mould with receptacles
  - Two-parted front layout
  - Front PCB with displays, keys and foot switch interface
  - Four setpoint potentiometers with turn knobs
  - Neutral electrode socket with insulation cup
  - Two monopolar combination output sockets
  - Monopolar foot switch socket with fixing plate
  - Bipolar output socket with fixing plate
  - Bipolar foot switch socket

1.5 Principle of Function

1.5.1 Microcontroller

The ME 401 offers two independent RF generators for monopolar and bipolar operation modes which are controlled central by a microcontroller system. The block diagram visualizes this. This central control also handles the front panel and the monitoring and control functions at the RF output PCB. The control performs the following functions:

- Self test of program memory and peripherals
- Self check with coded error messages
- Input of setting of the four setpoint potentiometers
- Output of set values to the LED displays
- Generation of the setpoint values for the RF generators
- Generation of compare setpoint values for the safety circuits

- Monitoring of the DC circuit parameters of the generators
- Input of front keying
- Lasting storage of front keying
- Input of finger and foot switch keying
- Coordination of control signals
- Activation of RF generators
- Setting of modulators
- Selection of operation mode of the ambivalent monopolar generator
- Activation of RF output relays
- Setting of frequency of the acoustic activation signal
- Change of loudness of the acoustic activation signal
- Activation of sound generator at NE alarm and power-on self test
- Setting of indicator lamps for RF activation and NE alarm
- Self-matching neutral electrode monitoring
- Optional automatc bipolar coagulation stop
- Monitoring and limitation of RF leakage currents
- Bipolar instrument identification

The control operates with two microcontrollers which have mutual communication exchange and share the tasks. This principle was preferred mainly because in this way a simpler and easier to overview concept of safety can be performed. Hereby the one controller (master controller) is superior to the other (slave controller).

Each of both controllers communicates with its peripherals via an own serial interface corresponding to the inter IC bus standard (I^2C bus). This bus consists of a synchronous clock line (SCL) and a bidirectional serial data line (SDA). All interface components are linked to this two lines. The clock generating component, in this case exclusively the actual microcontroller, is called to be the master and determines the data transfer at the bus. Data transfer is performed in eight bit long sequences (bytes), it will be initiated by the master by setting the lines to a certain condition (start condition S), followed by an address byte (device address) which selects a certain component and determines it to be data transmitter or data receiver. The receiving of a complete byte will be acknowledged by the receiver by setting both of the lines to a certain condition (acknowledge bit ACK). By setting of a further line condition (stop condition P), the data transfer will be closed.

Via both of this bus systems all input, output and monitoring will be performed. Only the setpoint values for the RF generators are transferred by own lines. So it is possible to perform the complete control wiring by a single flat cable which connects all boards which are part of the control periphery.

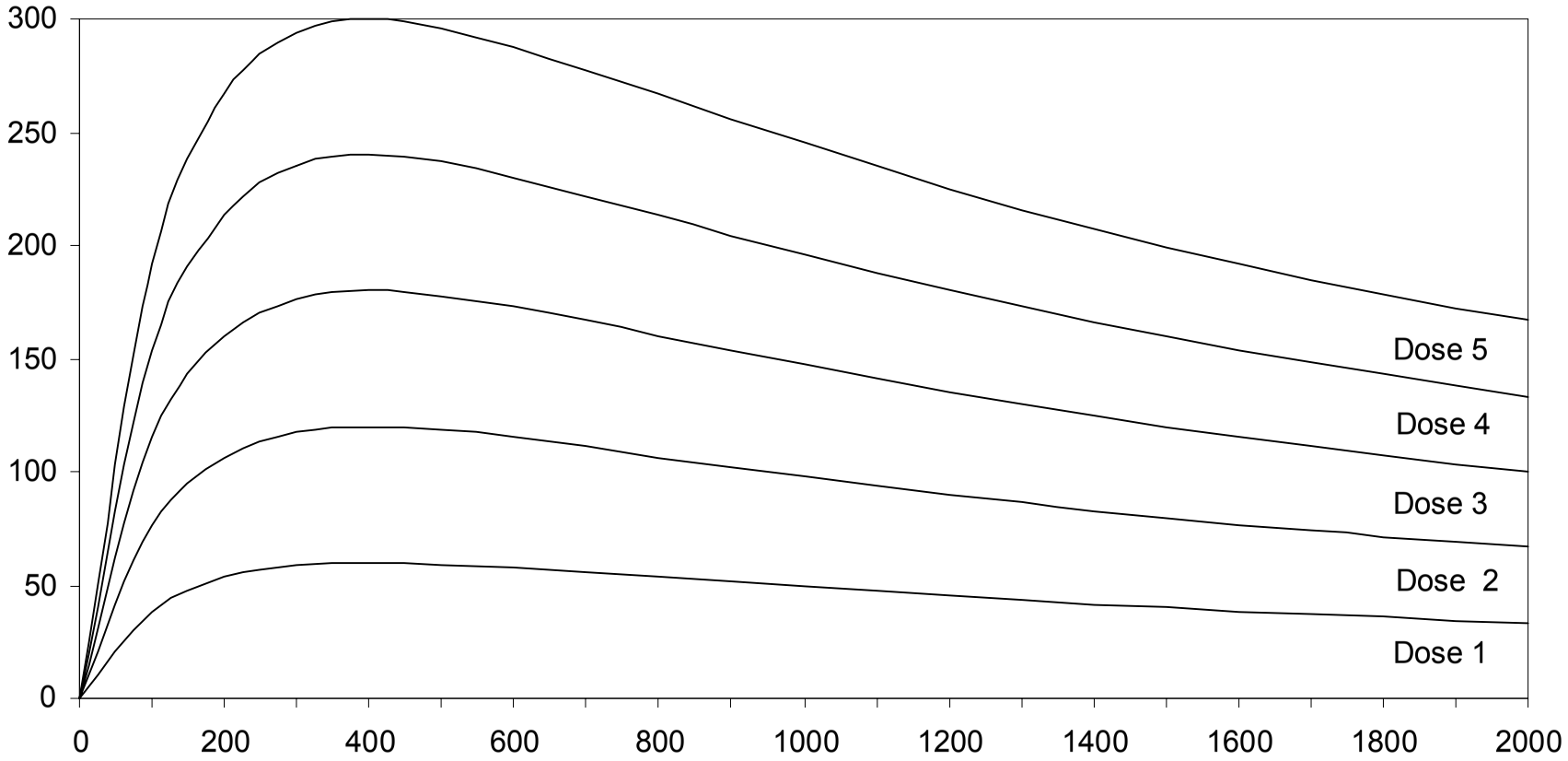
1.5.2 Principle of Control of Field of Characteristics

Basically, a RF surgery unit is a settable RF voltage source which is connected in serial with a matching resistor. This matching resistor is usual a reactive resistance performed by a capacitor. By this, the characteristic of the output power versus the output resistance shows the shape shown in the figure next page. There is a defined maximum of power in the area of the nominal matching resistance.

By cutting the almost kinds of tissue, the generator acts on an output resistance of 1000 to 1500 Ohms. This high value of resistance is a consequence of the steam leaving the tissue which acts like an insulation between cutting electrode and tissue. If the nominal matching resistance would be set in this range, this would cause problems to the start of the cutting process. The cutting process will be initiated by contact of the tissue with the electrode. Because of this direct contact, the output resistance is very low and is in the range of 100 to 200 Ohms. A sufficient high RF power must now establish steam formation and by this the change to high output resistance, but as is visible from the output characteristic, at this output resistance the generator is only able to deliver a fraction of its nominal output power, i. e. the generator is extremely mismatched. The cutting process will not progress. From this reason, a nominal matching somewhere between the extremes will be chosen, almost of 400 to 500 Ohms.

A probably way out of this dilemma may be a generator with controlled constant output power. Such a generator would have a constant output power over a wide range of output resistance, there would be no nominal matching resistance. A generator performed like this would show indeed a better performance when cutting would start, but the spark formation at the end of a cut is not acceptable in most cases.

From this reason, a combined voltage and power control is installed at the ME 401 which keeps the power constant for a mean range of output resistance. In the case of low and high output resistance the output power characteristic is voltage controlled. A generator like this is equipped with two regulators which must be supplied with two setpoint values. Here it is advantageous not to keep the relation of both of the setpoints constant over the whole area of power settings but to have a matched relation relative to the set power. By this the geometry of course of the power characteristic will change with power setting. So, to describe the output characteristic of the ME 401, a three-dimensional array of characteristics as scematically shown two pages further will be required.



Example for a voltage controlled characteristic

Example for a Field of Output Characteristics

1.5.3 Principle of Setpoint Generation

The principle is shown in the drawing next page. Setting of the output power at the ME 401 is performed by a rotary potentiometer which signal will be fed to the controller via I^2C-bus after A/D conversion with 8 bits. There the digital value forms a pointer to a single coloumn table (index table) with 256 rows which contents form a pointer to a set of four coloumn tables with 64 rows. Which table of this set will be selected depends on the selected current mode. The tables include the following values:

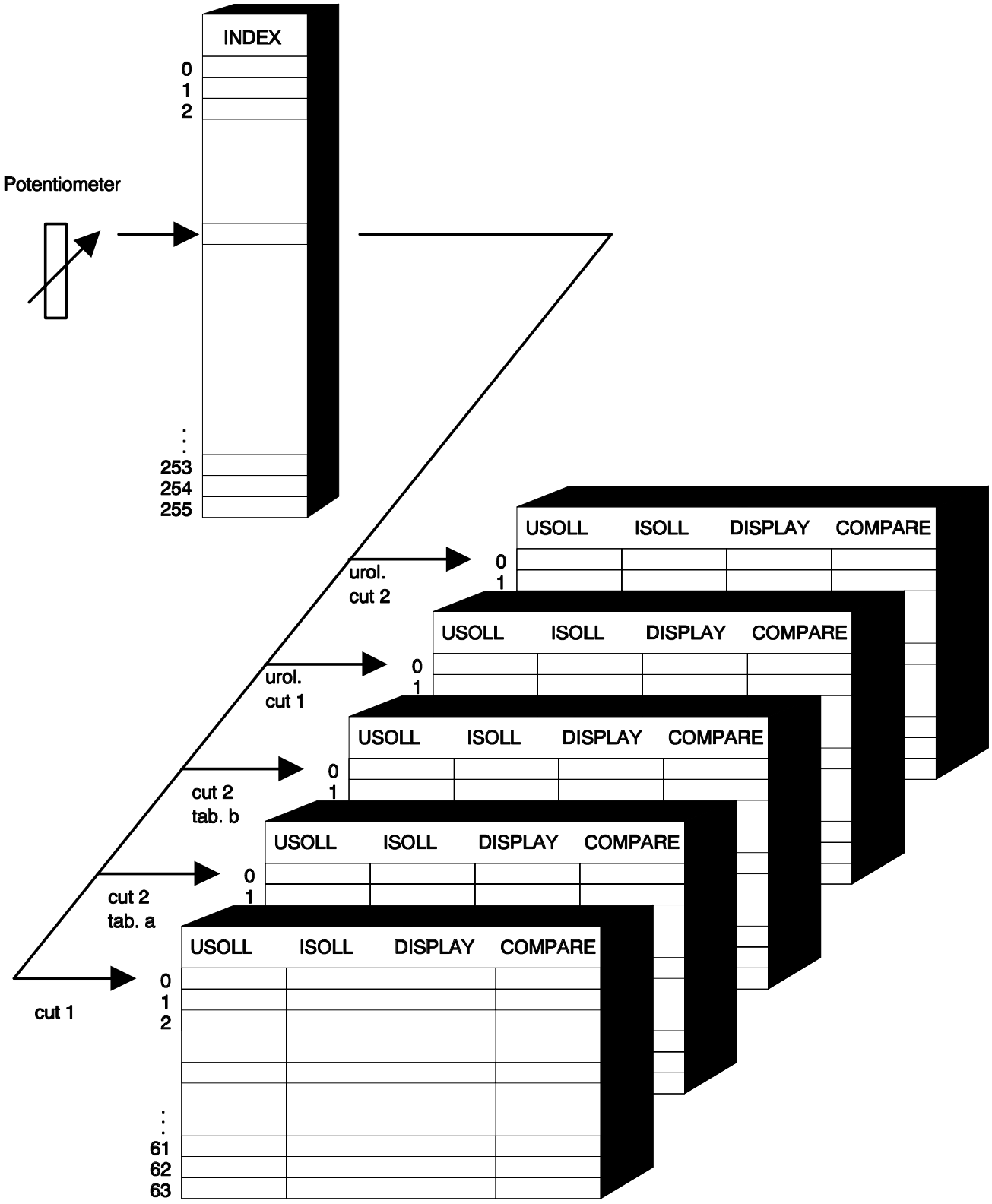
- USOLL: Numeric values from which the master controller generates the voltage setpoint values USM and USB for the respective RF generator for voltage limitation.
- ISOLL: Numeric values from which the master controller generates the current setpoint values ISM and ISB for the respective generator for power limitation.
- DISPLAY: Numeric values from which the slave controller generates the value which will be displayed as the power setting in the front panel.
- COMPARE: Numeric values from which the slave controller generates the compare setpoint values MCP and BCP for the power fault monitoring circuits.

This procedure enables a very flexible matching of the setpoint values to the different current modes. Additional to this table, there are the following single parameter:

- Degree of modulation (crest factor) of the selected current mode
- Threshold value for activation of RF leakage current limitation

The setpoint values are transferred to the RF generators not as analogue values but as pulse width modulated square wave signals USM and ISM or USB and ISB. Pulse width modulation is performed by the timers of the master controller which operate in the compare mode. This system has a product of resolution and pulse frequency of 1 MHz. Here, a resolution of 1000 increments at a pulse frequency of 1 kHz is performed. The advantage of this procedure is the noise immunity. Because a PWM signal can be fed via an optocoupler, a high immunity of the microcontroller system against fed back intrusions can be gained.

OPERATION MODE "MONOPOLAR CUTTING"



Principle of setpoint generation

1.5.4 Principle of RF Generation

The ME 401 offers two separated RF generators for monopolar and bipolar application which are identical from the basic circuit design. The monopolar generator is designed for an output power of 320 Watts, the bipolar for an output power of 80 Watts. The actual RF generator is a harmonic power oscillator (free running oscillator) in both cases. At the monopolar generator, this circuit will be changed to a flyback converter for spray coagulation, from HW 04 upwards also for monopolar coagulation 2 (ambivalent generator).

Controlling of the RF power is performed by a stepdown converter which is placed before the oscillator and controlled by two regulators in parallel. The one of the regulators controls the output voltage like in a switch mode power supply, the other one controls the output power by controlling the current which flows into the converter. If the converter is fed from a constant voltage and a sufficient constant degree of effectivity of the combination of converter and oscillator can be assumed, then the RF output power must be constant if the DC input power is controlled to be constant.

The two regulators are connected in a manner that each of them can reduce the converter setpoint, but cannot increase it against the action of the other one. The regulation loop is always closed only for one of the regulators. At very high and very low output resistances, the voltage regulator is valid, in the range between this ranges the power regulator is valid. The transition occurs at the kink points of the characteristic.

1.5.5 Safety Functions

Because a electrosurgery unit applies energy to a patient, there is principially the possibility of hazard for the patient, if this energy application occurs uncontrolled. From this reason there is a demand to reduce this risk by appropriate design as far as this is possible from the unit side.

The unit has to recognize and to control the following fault conditions:

- Unintended activation of RF power
- Higher output power than that of the set dose

The ME 401 offers a number of design arrangments to meet both of this aspects

An unintended activation may occur in three ways:

- Unintended operation of a finger or foot switch including the situation of "jamming" after intended operation because of a fault of the activation element

- Unintended activation as a result of a fault in the control signal path of the accessory outside the unit

- Unintended activation as a result of a fault in the signal path inside the unit

The first item cannot be monitored reliable by functions implemented in the unit. Any technical device is not in the position to argue whether an operation of a switch by external force was intended by the user or not. Furthermore, a technical device cannot differ between an intended activation of a switch and a short circuit in the cable or a rupture of a reset spring in the switch mechanism. From this reason, the user has to be involved into the decision of having a fault condition or not.

Usual, RF units are equipped with an acoustic indication of activation which enables the user to recognize activation even when unintended. So the safety problem is transferred to the reliability of the acoustic indication.

At the ME 401 the acoustic signal is generated by a sound generator programmable by the controller. Activation of this sound generator may occur either by the control or directly by the signals HM and HB of the RF generators. A fault in the course of the controller's program cannot prevent activation of sound caused by HM or HB, but the frequency in the possible range may be undefined.

The function of the control signals HM and HB will be checked during the power-on selftest by activating both of the RF generators while the output relays remain opened.

Occurence of an overranged output power may be caused by the following fault conditions:

- Damage at one of the setpoint potentiometers or at its connection cable

- Disturbance in the analogue value transmission to the controller

- Fault in one of the setpoint tables

- Fault in one of the controllers or their operation codes

- Fault in the RF generator setpoint transmission

- Fault in the power controller

- Fault in the feedback value monitoring of the regulators

- Fault in the pre-voltage regulation

- Fault in the DC power converter

The most weighty fault to be assumed is a longitudinal short circuit of the DC power converter with the consequence of unlimited maximum output power with values beyond the nominal maximum power. From this reason, this fault should not only be recognized by the unit but controlled.

In the ME 401 this is performed by a relay K1 placed in the energy flow path of the RF generators and additional by the high voltage relays in the RF output circuits.

A problem herein is the safety of keeping the monitoring circuit available for the case of fault, that it would not become inactive by an undetected fault. So, for the ME 401 the following safety philosophy is valid:

- If there is a single fault resulting in an uncontrolled increase of output power, the unit must be in the position to recognize and control this condition.
- A single fault which results in a failure of the monitoring system must be recognized during the next power-on self test. It is supposed that maximal one fault will occur during one operation period of the unit.

The safety arrangements installed at the ME 401 can be classified in three sections:

- Monitoring of the setpoint value generation
- Monitoring of the control
- Monitoring of the power stages

The setpoint value generation will be monitored by double transmission of the analogue values with consecuting comparision, the potentiometers will be monitored for interruptions in their circuits. The setpoint tables will be checked for alterations during the power-on selftest.

The control consists of two microcontrollers which share their tasks. The correct execution of the operation code will be monitored by a watchdog circuit. The correct communication of both of the microcontrollers will also be monitored. An additional monitoring happens implicit by the compare signals MCP and BCP which have to vary their values periodically between zero and their nominal values else RF generation cannot occur.

Monitoring of the power stages is performed by monitoring the level of the pre-regulated voltages UFM and UFB. Current will be monitored by inductive current transducers which are double for separate current measure for power regulator feedback and for power monitoring else its failure would not be recognizable. Monitoring of the output power is performed by a comparator by means of the current values IFM or IFB and the compare setpoint values MCP or BCP. The compare setpoint value is a square wave signal with a frequency of approx. 33 Hz with the lower level near zero and the upper level always somewhat higher than the maximum current value in the fault-free condition. So, a square wave signal occurs at the output of the comparator which is fed to a driver circuit. The output signal of this driver will be rectified and forms the energy required to energize the relay K1 in the energy flow path and by forming the signals R1 or R2 also for the relays in the RF output circuits.

In a fault condition the current value is higher than the compare setpoint value. Instead of a square wave signal, the comparator produces a DC signal which the following rectifier cannot use and releases the relays.

In case of a longitudinal short circuit of the DC power converter, the inductive current transducers will produce no output signal and so will not monitor this fault condition. In this case, the no more controllable voltage UIM or UIB at the output of the DC power converter will increase above the setpoint which makes the voltage regulator run to its lower boundary.

The fault monitoring comparator is an "open collector" type component which gets its pullup voltage required to feed the following driver from the output of this regulator. If the output voltage of that will decrease to zero, there is no more feeding of the following driver and the relay K1 will be released.

At the ME 401, a fault occuring in a RF generator or its RF output circuit cannot result in a power increase because there is no appreciable additional power input to this stages.

1.6 Circuit Description

The basic mode of operation and wiring of the ME 401 is visible from the block circuit diagram and the wiring diagram on the next pages.

1.6.1 Signal Bus

The control signal lines are confined to a bus cable with 26 lines which connects all boards except the standby PCB with plug connectors. There where a bus line has connection to the inner circuit of the board, this is marked with a filled circle.

The function of the signals at the bus cable are denoted as follows:

- GND (pins 1, 7, 10 and 16): Signal ground and negative pole of auxiliar power supply.
- E (pin 24): Guarding for leakage currents, not used as a bus line.
- +IIC (pins 9 and 12): 5V suppy of inter IC bus interface components, generated at the controller PCB.
- +5D (pin 8): 5V supply of the LED displays for power settings at the front panel. Is connected to +IIC at the controller PCB and guided separate from +IIC for discoupling because of high power consumption.
- +15M (pin 15) 15V supply of the monopolar RF generator PCB, is generated at the controller PCB together with +15B and +15H but guided separate for discoupling.
- +15B (pin 19) 15V supply of the bipolar RF generator PCB, is generated at the controller PCB together with +15M and +15H but guided separate for discoupling.

- +15H (pin 11) 15V supply of the RF output and the front PCBs, is generated at the controller PCB together with +15M and +15B but guided separate for discoupling.

- SDA1 (pin 2): Serial data line of the I^2C bus 1 of the master controller at the controller PCB.

- SCL1 (pin 3): Synchronous clock line of the I^2C bus 1 of the master controller at the controller PCB.

- INT1 (pin 4): Interrupt request line of the I^2C bus 1, not used at the ME 401.

- SDA2 (pin 5): Serial data line of the I^2C bus 2 of the slave controller at the controller PCB.

- SCL2 (pin 6): Synchronous clock line of the I^2C bus of the slave controller at the controller PCB.

- USM (pin 13): Pulse width modulated square wave signal of the timer 1 of the master controller for generation of the monopolar voltage setpoint value.

- ISM (pin 14): Pulse width modulated square wave signal of the timer 2 of the master controller for generation of the monopolar current setpoint value for power regulation.

- USB (pin 17): Pulse width modulated square wave signal of the timer 3 of the master controller for generation of the bipolar voltage setpoint value.

- ISB (pin 18): Pulse width modulated square wave signal of the timer 4 of the master controller for generation of the bipolar current setpoint value for power regulation.

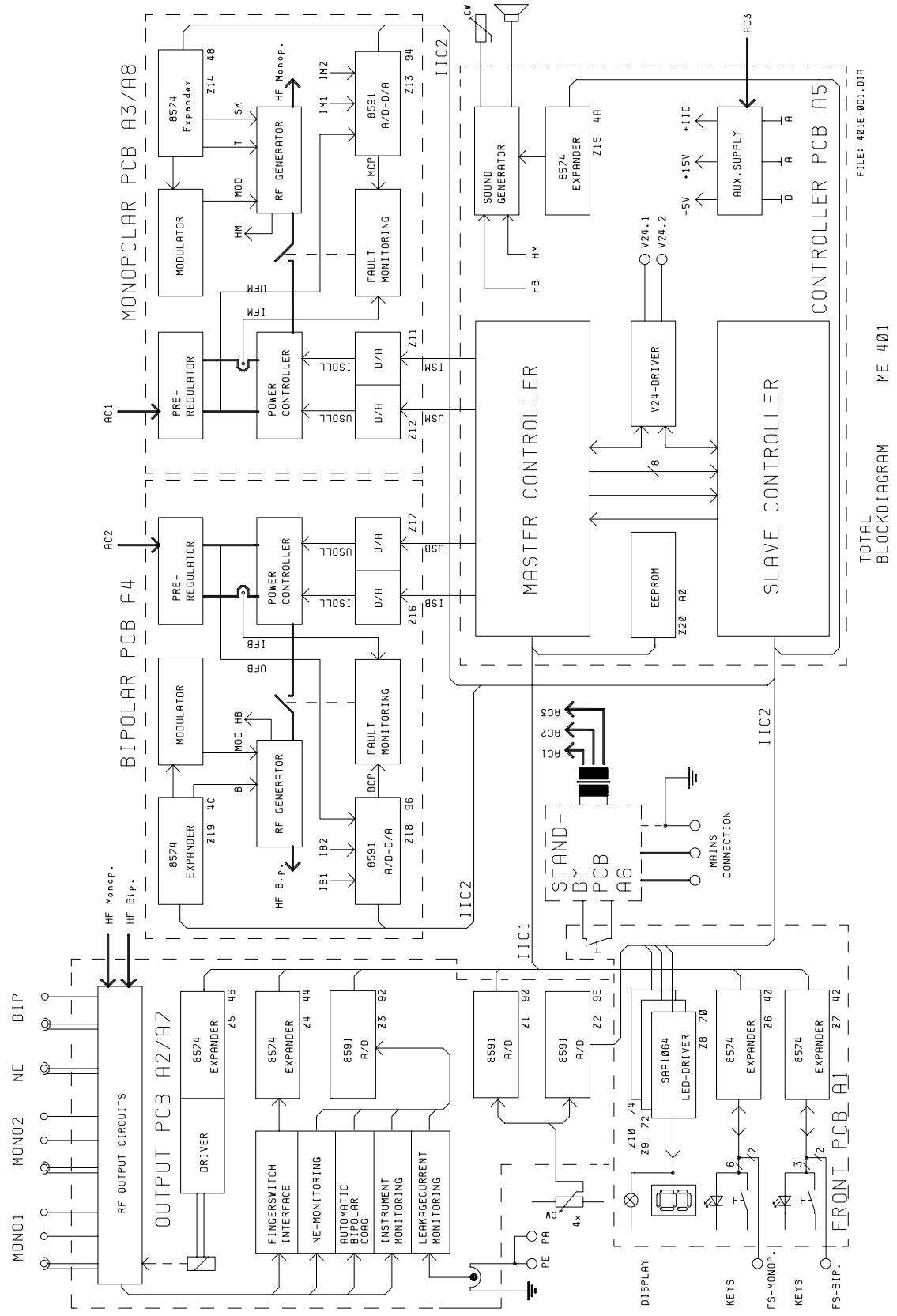
- R1 (pin 20): Output signal of the monopolar power fault monitor, establishes the auxiliar energy for energizing the relays in the monopolar output circuit, is a square wave signal in normal condition and a DC voltage of 0V or 15V in fault condition.

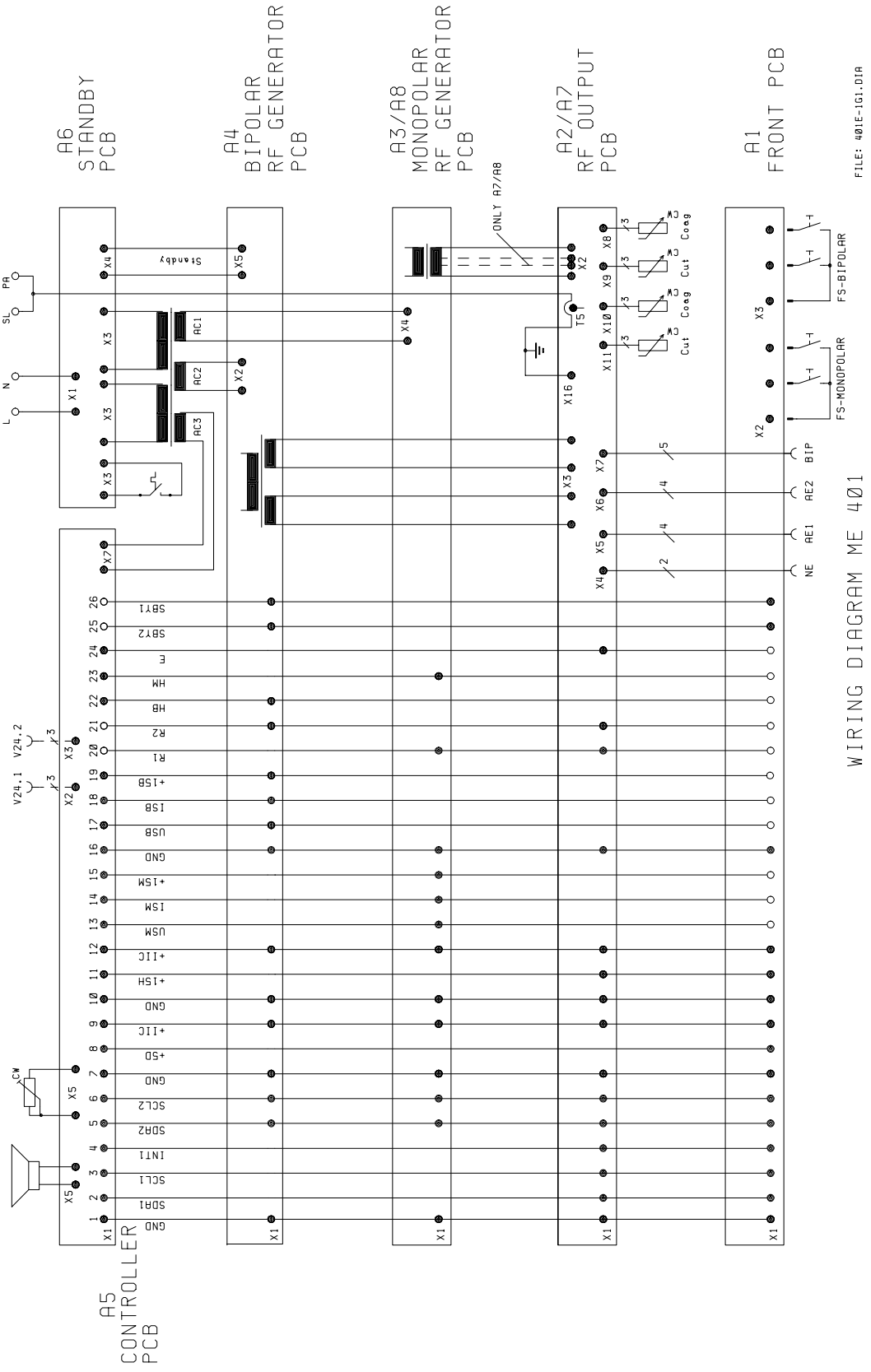
- R2 (pin 21): Output signal of the bipolar power fault monitor, establishes the auxiliar energy for energizing the relays in the bipolar output circuit, is a square wave signal in normal condition and a DC voltage of 0V or 15V in fault condition.

- HM (pin 23): Will be generated in the monopolar RF generator and indicates the presence of monopolar RF voltage, activates directly the sound generator at the controller PCB.

- HB (pin 22): Will be generated in the bipolar RF generator and indicates the presence of bipolar RF voltage, activates directly the sound generator at the controller PCB.

- SBY1, SBY2 (pins 25 and 26): Current loop of the standby circuit to the Standby key at the front PCB, is guided from the front PCB via bipolar RF generator PCB with a twin line cable to the standby PCB.


MONOPOLAR PCB A3/A8
BIPOLAR PCB A4
OUTPUT PCB A2/A7
FRONT PCB A1
CONTROLLER PCB A5
STAND-BY PCB A6
TOTAL BLOCKDIAGRAM ME 401
FILE: 401E-0D1.DIA
MASTER CONTROLLER
SLAVE CONTROLLER
PRE-REGULATOR
POWER CONTROLLER
MODULATOR
RF GENERATOR
FAULT MONITORING
8574 Expander
8591 A/D-D/A
SOUND GENERATOR
AUX.SUPPLY
V24-DRIVER
EEPROM
RF OUTPUT CIRCUITS
DRIVER
FINGERSWITCH INTERFACE
NE-MONITORING
AUTOMATIC BIPOLAR COAG
INSTRUMENT MONITORING
LEAKAGECURRENT MONITORING
SAA1064 LED-DRIVER
MAINS CONNECTION
DISPLAY
KEYS
FS-MONOP.
FS-BIP.
MONO1
MONO2
NE
BIP
HF Monop.
HF Bip.
IIC1
IIC2


A6
STANDBY
PCB
A4
BIPOLAR
RF GENERATOR
PCB
A3/A8
MONOPOLAR
RF GENERATOR
PCB
A2/A7
RF OUTPUT
PCB
A1
FRONT PCB
A5
CONTROLLER
PCB
ONLY A7/A8
FILE: 401E-1G1.DIA
WIRING DIAGRAM ME 401
FS-BIPOLAR
FS-MONOPOLAR
Standby
Coag
Cut
BIP
AE2
AE1
NE
PA
SL
N
L
GND
SDA1
SCL1
INT1
SDA2
SCL2
GND
+5D
GND
+IIC
GND
+15H
+IIC
USM
ISM
+15M
GND
USB
ISB
+15B
R1
R2
HB
HM
E
SBY2
SBY1

1.6.2 Front PCB

The front PCB contains the display elements and operation keys and forms the interface to the controller for this elements as well as for the foot switches. There are the following components:

- Display circuit for monopolar cutting
- Display circuit for monopolar coagulation
- Display circuit for bipolar operation modes
- Keys and foot switches for monopolar operation modes
- Keys and foot switches for bipolar operation modes
- Standby key

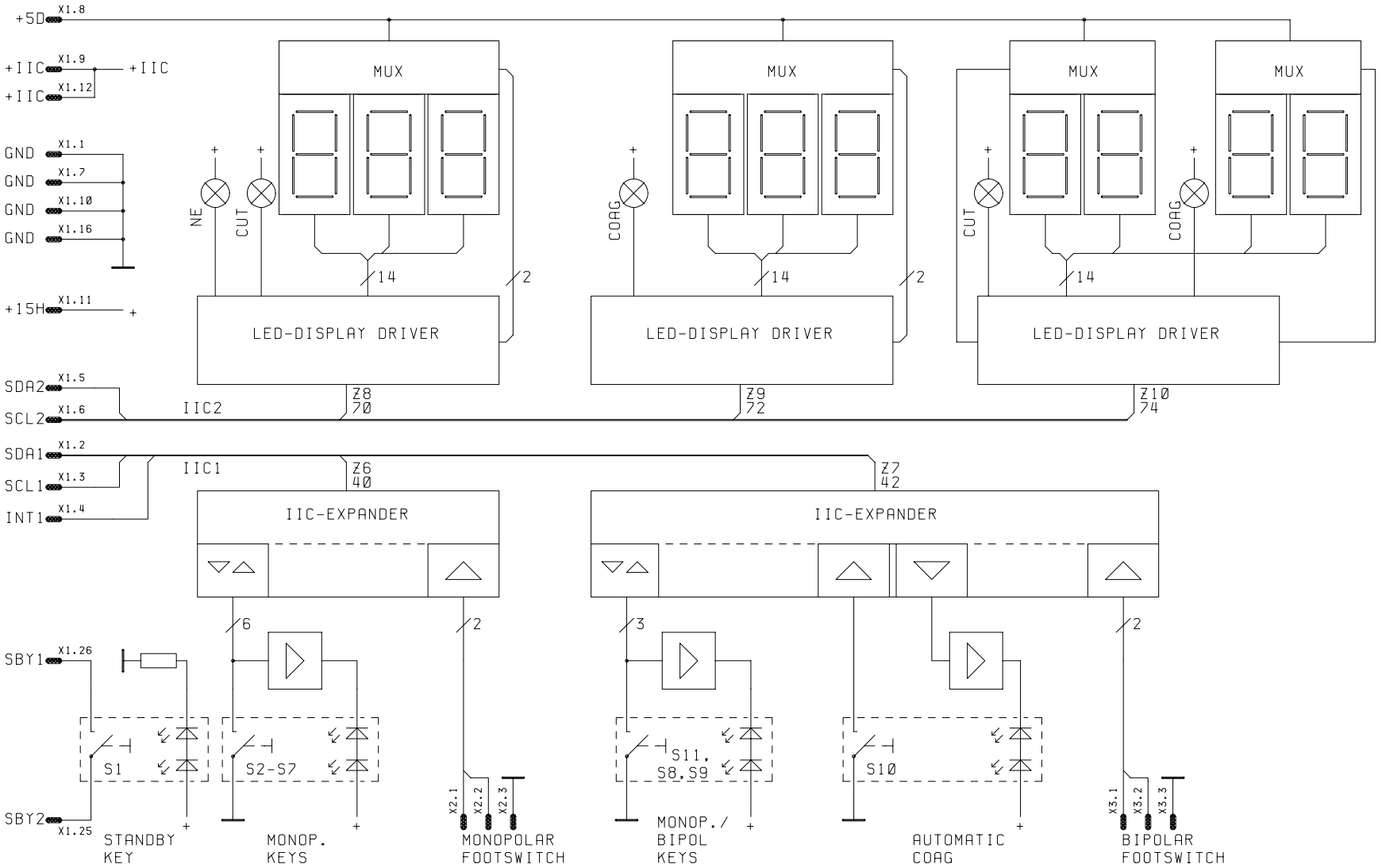
The monopolar display circuits consist of three digit green seven segment LED displays which will be driven by a segment driver with I^2C interface in a two rows/two lines multiplex mode for each circuit, Z8 and Z9. The segment outputs which else would drive the decimal points not used here drive the indicator lamps for cutting activation and neutral electrode alarm in the cutting circuit and the indicator lamp for coagulation activation in the coagulation circuit. This is outside the multiplexer mode, i. e. the brightness can be set to zero, half and full by setting the corresponding registers. In case of the NE lamp, this feature is used.

The bipolar display circuit has the same structure. Both of the two digit LED displays are driven from a common segment driver Z10 which also drives the activation indication lamps.

The keys used in the ME 401 have an illuminated keying pad, the lighting of which indicates the set operation mode. Request of a key and drive of its illumimation via the same line is performed by the bidirectional I^2C bus expanders Z6 and Z7. To enable a key to be requested, the expander port connected to it must be set on "high" level. Then the associated key pad illumination is dark. On keying the port will be pulled down to "low" level, the key will light up. By repetitive request of the expander port state the controller recognizes this change in state and sets the output register associated with this port line to "low" level, so that this state remains after releasing the key, additional the other port lines belonging to the same block of current modes will be set back to "high" level.

The key S10 for setting on/off of the automatical bipolar coagulation is operated in the toggle mode and has separated lines for key request and key pad illumination.

The foot switch signals are also requested by the I^2C bus expanders.



BLOCKDIAGRAM

FILE= 401US-3E.dia

FRONT PCB A1

ME 401

1.6.3 Radio Frequency Output PCB

The output PCB can be classified in three sections:

- Monopolar output circuit with periphery
- Bipolar output circuit with periphery
- Control interface with setpoint value input

The monopolar output circuit consists of the functional sections as follows:

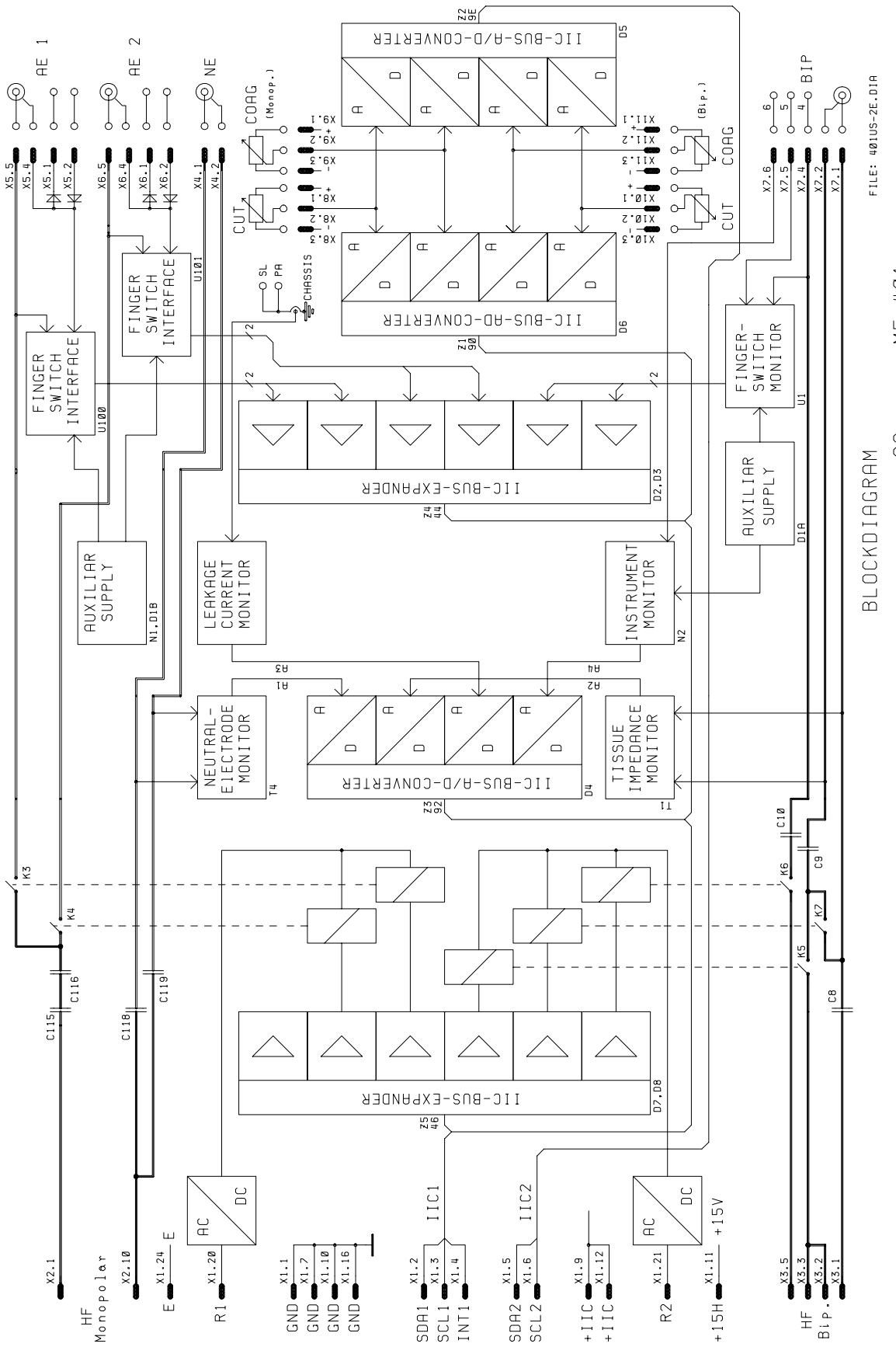
- Energy flow path with matching capacitors and relays
- Finger switch interface for output 1
- Finger switch interface for output 2
- Monopolar auxiliar supply
- Neutral electrode monitor
- Leakage current monitor

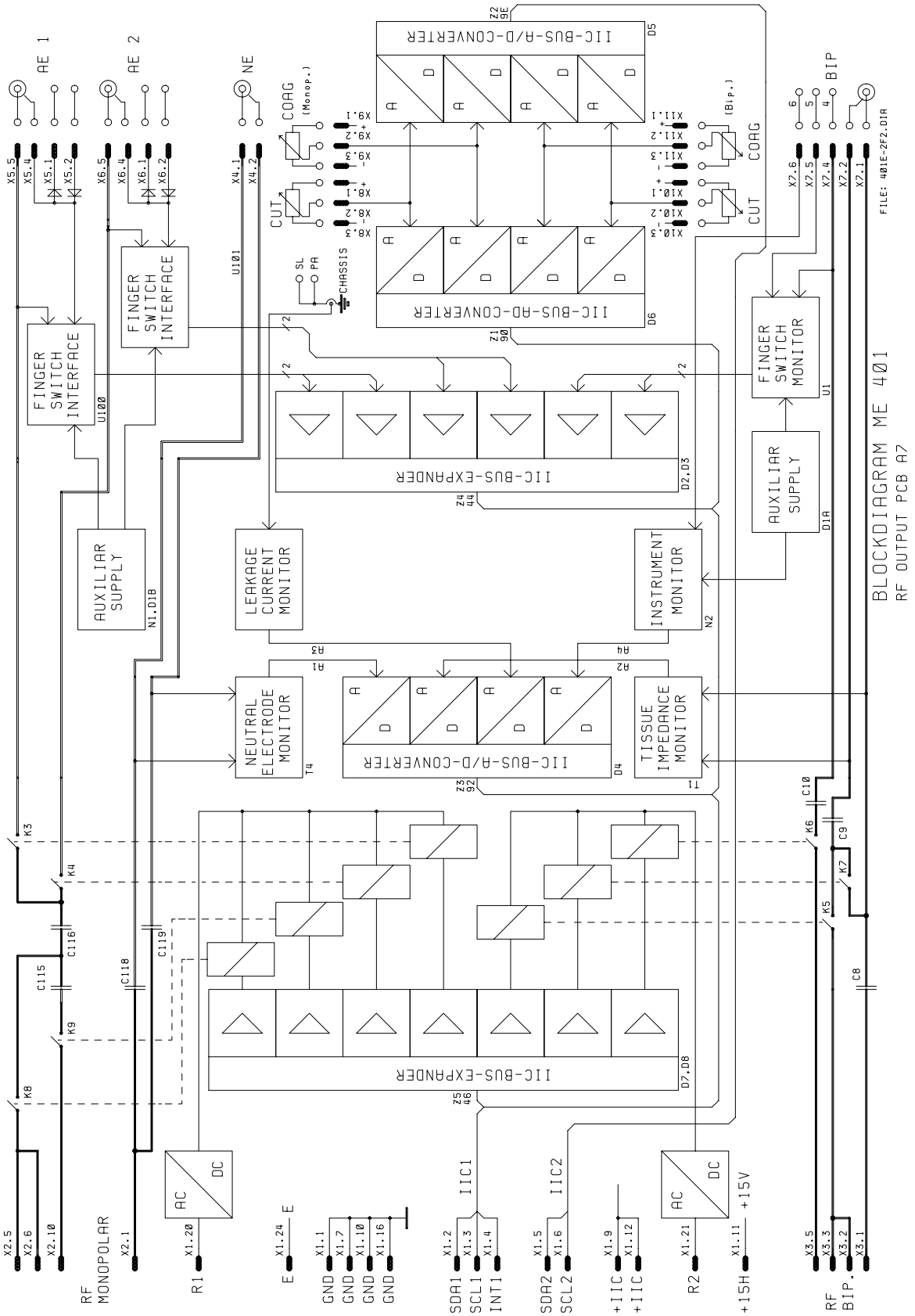
Via the high voltage relays K3 or K4, the energy flow will be fed to one of both outputs AE1 and AE2. With the recent RF output PCB A7 (from hardware state 04), the relays K8 and K9 select one of the output matchings of the generator.

For activation of RF power by finger switches at the handpiece,two interface circuits are installed which transfer the control signals by means of special optocouplers over the 32 millimeter insulation barrier in compliance with the IEC 601 recommendations. For transferring two control signals over a two-wire cable, a current direction encoding in the handpiece is done which must be decoded in the interface circuit by two signal pathes with contrary current conduction direction. To gain compatibility with the three-pin connectors which are common in the US market, this encoding must be performed supplementary by means of two diodes.

A small converter supplies this circuits, its output voltage is transferred over the insulation barrier by a transformer.

Monitoring of the neutral electrode for correct application is performed by monitoring the impedance between the both of the cord lines. For this purpose, a small harmonic oscillator with high source resistance generates an AC voltage which is applied to the electrode cord lines by a transformer. Besides, this AC voltage will be rectified and fed to the controller. Corresponding to the shunt formed by the applied electrode, this oscillator will be more or less damped what has an effect on the level of the rectified voltage.


BLOCKDIAGRAM
RF OUTPUT PCB A2
ME 401
FILE: 401US-2E.DIA
AE 1
AE 2
NE
COAG
CUT
BIP
IIC-BUS-A/D-CONVERTER
IIC-BUS-AD-CONVERTER
IIC-BUS-EXPANDER
FINGER SWITCH INTERFACE
FINGER-SWITCH MONITOR
AUXILIAR SUPPLY
LEAKAGE CURRENT MONITOR
INSTRUMENT MONITOR
NEUTRAL-ELECTRODE MONITOR
TISSUE IMPEDANCE MONITOR
CHASSIS
AC
DC
HF Monopolar
E
R1
GND
IIC1
SDA1
SCL1
INT1
IIC2
SDA2
SCL2
+IIC
R2
+15H
+15V
HF Bip.


BLOCKDIAGRAM ME 401
RF OUTPUT PCB A7
FILE: 401E-2F2.DIA
AE 1
AE 2
NE
BIP
COAG (Monop.)
CUT
(Bip.)
CUT COAG
CHASSIS
SL
PA
FINGER SWITCH INTERFACE
FINGER SWITCH MONITOR
IIC-BUS-A/D-CONVERTER
IIC-BUS-EXPANDER
AUXILIAR SUPPLY
LEAKAGE CURRENT MONITOR
INSTRUMENT MONITOR
NEUTRAL ELECTRODE MONITOR
TISSUE IMPEDANCE MONITOR
AC DC
RF MONOPOLAR
R1
E
GND
IIC1
SDA1
SCL1
INT1
IIC2
SDA2
SCL2
+IIC
R2
+15V
RF BIP.

To meet the limitations for RF leakage currents in compliance with the IEC 601 standard, the ME 401 offers an active RF current limitation. For this purpose, the RF leakage current returning to the unit via PE or PA conductor will be monitored by a current transducer, the output signal of it is fed to the controller. This demands the case to be grounded **only by the protection earth conductor** else the leakage current monitor would be shunted. From this reason, the eqipotentiol connector and the receptacles for underground fixing are insulated. If the unit is proposed to be fixed with its case by screws or else, please contact the MARTIN Service Center or sales office.

The bipolar output circuit and its periphery consists of functional sections as follows:

- Energy flow path with matching capacitors and relays
- Finger switch interface
- Bipolar instrument identification
- Bipolar auxiliar supply
- Tissue impedance monitor

Because of the strong different matching, the energ flow path for bipolar coagulation and bipolar cutting is splitted. At coagulation, K5 is closed, the coagulation voltage is present between pins 1 and 2 of the output connector X7. At cutting, K6 and K7 are closed, the cutting voltage is present between pin 4 and the pins 1 and 2 which are RF connected.

The bipolar finger switch control acts exactly like the monopolar ones with current direction encoding. The circuit is identical to that of the monopolar section.

For identification of a bipolar instrument connected to the unit, a resistor may be connected between pin 6 and pin 7 of X7. This resistor controls the frequency of a multivibrator, its output signal will be transferred over the insulation barrier by an optocoupler. Mean value formation from this square wave signal generates a DC signal which corresponds to the resistor value and will be fed to the controller.

A small converter supplies the finger switch control circuit and the instrument identification monitor, its output voltage will be transferred over the insulation barrier by a transformer.

To stop coagulation automatically, the tissue impedance between the bipolar electrodes will be monitored, the signal is fed to the controller. For impedance monitoring, the same circuit as for NE monitoring is used, but the interpretation of the signals by the controller is different.

The controller interface consists of the functional sections as follows:

- Control of the relays in the energy flow paths
- Finger switch signal request
- Request of analogue signals from NE monitor, tissue impedance monitor, RF leakage current and instrument identification
- Request of setpoint potentiometer analogue values

The output relays are controlled by the I^2C bus expander Z5.

The finger switch signals will be requested by the I^2C bus expander Z4.

The analogue values of the monitors will be converted by a four-channel eight bit A/D converter with I^2C interface Z3 and transmitted to the controller.

For safety reasons, the analogue values of the setpoint potentiometers are transmitted on two separated paths. Once, the four channel A/D converter Z1 converts and transmits the values via I^2C bus 1 to the master controller, twice Z2 converts and transmits the values via I^2C bus 2 to the slave controller. The inputs of both converters are discoupled by resistors.

At the ends of the potentiometers small resistors are placed which effect that the digital values 00H, 01H, 02H as well as FDH, FEH and FFH cannot occur in normal condition. Their occurence announces an interruption of a potentiometer line. On rupture of the low side potentiometer line, the slider potential will be full positive potential (FFH). On rupture of the high side line, the slider potential will be ground potential (00H). On interruption of the slider line, pulldown resistors at the converter inputs set them to ground potential (00H). This enables the controller to recognize a potentiometer circuit fault.

1.6.4 Monopolar RF Generator PCB

The monopolar RF generator PCB is a complete unit for controlled generation of RF power from an AC power supply. It consists of the following functional sections:

- Rectifier and voltage pre-regulation
- DC power converter
- PWM demodulators
- Power oscillator, changeable to flyback converter
- Modulator
- Controller interface for activation and settings
- Fault monitor

The pre-regulation is performed by a stepdown DC converter controlled by a regulator to produce a voltage of 44V.

The DC power converter is identical to the pre-regulator with respect to the energy flow path and the kind of control. It will be controlled by a combined voltage/current regulator. The voltage regulator limits the output voltage of the DC power converter. When it is operative, a red LED will light. The current regulator limits the current flowing into the DC power converter and so the DC power. When it is operative, a green LED will light.

The current value is monitored by a current transducer.

The regulators get their setpoint values from the demodulators Z11 and Z12 which transform the PWM square wave signals USM and ISM into analogue voltages.

The RF generator is a free running power oscillator which feeds to a tank circuit. By the square wave signal MOD the feedback paths can be made and broken periodically which makes the oscillator being keyed on and off. In this way the modulation of RF voltage for eschar forming cutting is performed.

Activation of the signal SK energizes a relay which switches the oscillator to a flyback converter. By this way high voltages at low mean power (high crest factor) is easier to be gained. The generator will then be controlled by the modulator.

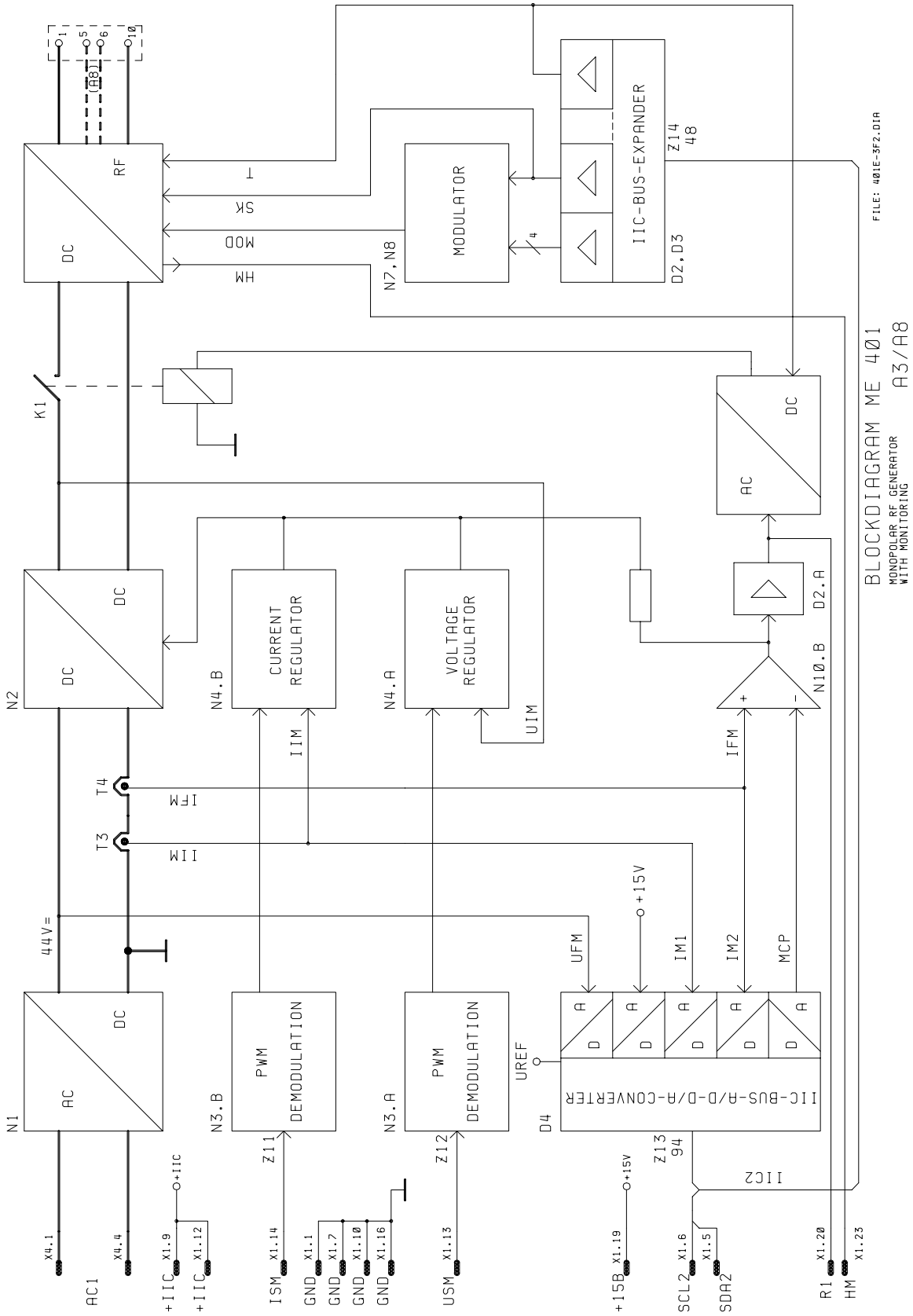
The modulator is a pulse width modulator which can be activated by the controller via I^2C expander Z14 in alignable fix degrees of modulation. Via the expander the signal T activates the generator.

For protection against overrated output power some of the parameters are monitored by the controller via the four channel A/D converter Z13:

- Pre-regulated voltage UFM
- Reference voltage UREF
- Actual current value IM1
- Actual compare current value IM2

Because the power fault comparator circuit monitors only the current value, it is possible that output power increases as a result of increase of the pre-regulated voltage because of a fault. From this reason this voltage has to be monitored additionally.

An increase of output power caused by an increase of the reference voltage UREF would not be recognized by the power fault monitor because it uses this voltage as reference for own. So it will be monitored in an indirect manner by monitoring the ratio between UREF and the 15V auxiliar supply. If the monitored 15V would decrease, the controller would interprete this as an increase of UREF.


BLOCKDIAGRAM ME 401
MONOPOLAR RF GENERATOR
WITH MONITORING
A3/A8
FILE: 401E-3F2.DIA
RF
DC
AC
K1
N1
N2
N3.A
N3.B
N4.A
N4.B
N7,N8
N10.B
D2,D3
D2.A
D4
Z14
48
Z13
94
Z11
Z12
MODULATOR
IIC-BUS-EXPANDER
CURRENT REGULATOR
VOLTAGE REGULATOR
PWM DEMODULATION
IIC-BUS-A/D-D/A-CONVERTER
T1
SK
MOD
HM
T4
T3
IFM
IIM
UIM
UFM
UREF
+15V
IM1
IM2
MCP
IIC2
44V=
AC1
X4.1
X4.4
+IIC
X1.9
X1.12
ISM
X1.14
GND
X1.1
X1.7
X1.10
X1.16
USM
X1.13
+15B
X1.19
SCL2
X1.6
SDA2
X1.5
R1
X1.20
HM
X1.23

A failure of the current probe circuit may lead to a not recognizable double fault. Because of that the current probe circuit is double. The probe values of both circuits will be compared.

Output power monitoring is performed by a comparator which compares the actual current value with a compare value which is generated by the A/D-D/A converter Z13 as a square wave signal. This square wave signal swings between a voltage near zero and the analogue value of the compare value from the ROM tables. As long as the actual current value is smaller than the square wave amplitude, a square wave signal is generated at the comparator output which will be amplified by the following driver and from which the following rectifier forms a voltage to energize the relay K1. This signal forms as output signal R1 also the auxiliar energy to energize the relays in the monopolar output circuit at the output PCB.

In case of a shorted DC power converter the current transducers will produce no output signal and the fault comparator will not recognize this severe fault. In this case the voltage regulator of the DC power converter will run to its lower boundary because it recognizes a too high actual output voltage. The missing IFM signal voltage disables the driver to be fed.

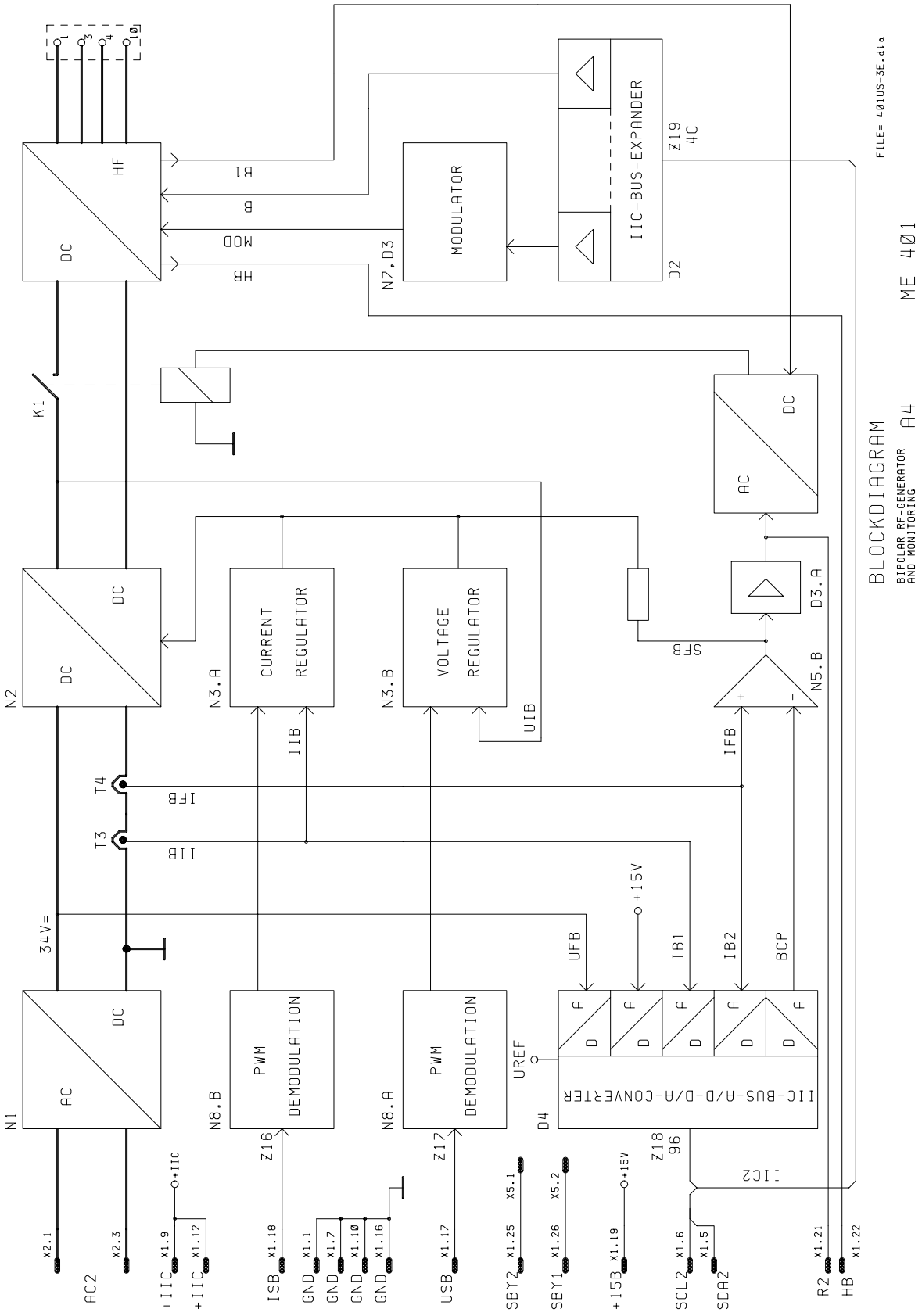
1.6.5 Bipolar RF Generator PCB

The structure of the bipolar RF generator is identical to that of the monopolar generator except the ability of being switched to a flyback converter. Because of the lower power level, the energy flow path is performed by other means. There are the functional blocks as follows:

- Rectifier and voltage pre-regulation
- DC power converter
- PWM demodulators
- Power oscillator
- Modulator
- Interface for activation and setting
- Fault control monitoring circuit

The voltage pre-regulation is performed here with a monolithic integrated switch mode power controller as well as the consecutive DC power converter. Regulation, the mode of actual value registration and demodulation of the setpoint signals is identical to that of the monopolar generator.

The RF generator is a harmonic power oscillator which feeds to a tank circuit. The modulator is basically the same as with the monopolar generator but only with one settable degree of modulation. Activation of the modulator is performed by the I^2C bus expander Z19 which also activates the oscillator by means of the signal B.


BLOCKDIAGRAM
BIPOLAR RF-GENERATOR
AND MONITORING
A4
ME 401
FILE= 401US-3E.dia
HF
DC
MODULATOR
IIC-BUS-EXPANDER
Z19
4C
D2
N7,D3
K1
AC
N2
CURRENT
REGULATOR
N3.A
VOLTAGE
REGULATOR
N3.B
D3.A
N5.B
SFB
UIB
IIB
IFB
T4
T3
34V=
+15V
UFB
IB1
IB2
BCP
N1
PWM
DEMODULATION
N8.B
N8.A
UREF
D4
IIC-BUS-A/D-D/A-CONVERTER
Z18
96
IIC2
Z16
Z17
AC2
X2.1
X2.3
+IIC
X1.9
X1.12
ISB
X1.18
GND
X1.1
X1.7
X1.10
X1.16
USB
X1.17
SBY2
X5.1
X1.25
SBY1
X5.2
X1.26
+15B
X1.19
SCL2
X1.6
SDA2
X1.5
R2
X1.21
HB
X1.22

The monitoring circuit is identical to that of the monopolar generator. It generates an output signal R2 which forms the auxiliar power for energizing the relays in the bipolar output circuit at the RF output PCB.

1.6.6 Controller PCB

At the controller PCB, there are three functional sections:

- Microcontrollers
- Sound generator
- Auxiliar power supplies

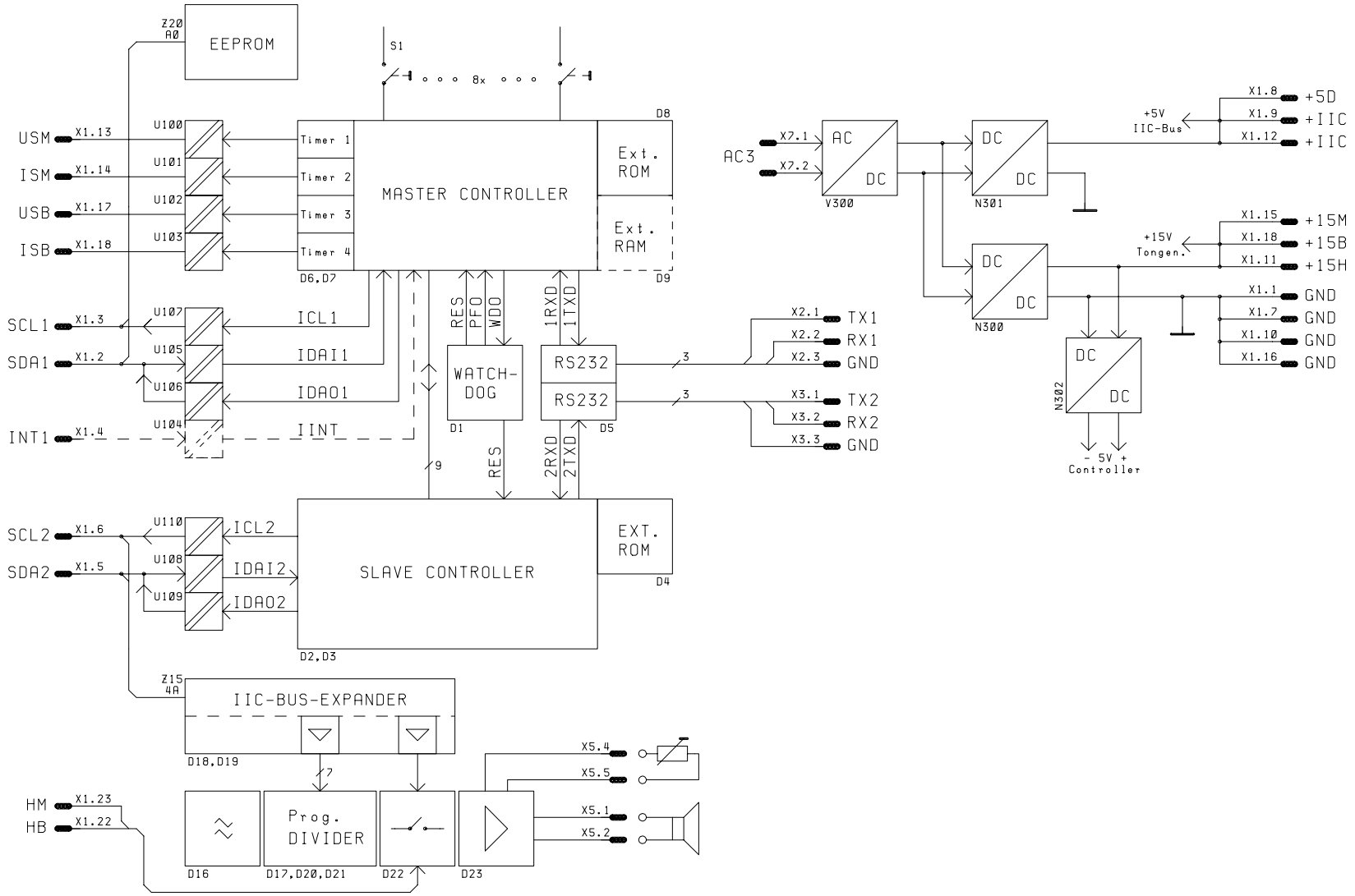
The intrinsic controller consists of the functional sections as follows:

- Master controller
- Slave controller
- Watchdog
- Twin RS 232 interface (not used)
- Setpoint interface
- I^2C bus interface 1
- I^2C bus interface 2
- EEPROM

The master controller with program and tables memory generates the setpoints for the RF generators by means of its four programmable timers and drives the I^2C bus 1. One of its parallel ports is connected to an eightfold DIL switch for special changes in operation mode. Optional, an additional external RAM can be installed, a feature which is not used at present.

The slave controller drives the I^2C bus 2. Master and slave controllers communicate via one of their parallel ports.

The watchdog is basically a monostable multivibrator which has to be retriggered by the master controller within a determined time else it releases a reset of both microcontrollers. This shall ensure that the master controller will not be caught in an endless program loop due to any disturbance. For the slave controller, the master controller acts as a watchdog.



BLOCKDIAGRAM

CONTROL, AUXILIAR SUPPLY, SOUND GENERATOR A5 ME 401

FILE: 401US-2E.DIA

Both of the controllers are connected to an RS 232 driver. At present, this interface is only for development purposes, it is not fed out of the unit.

A big problem especially in case of electrosurgical units are electromagnetic disturbances as produced by the unit itself and which may result in transmission errors of digital signals. This results mainly from the unavoidable RF leakage currents as well as from the powerelectronic stages.

Because of that, all signals which leave or enter the controller have a galvanic separation by optocouplers. Into the controller core, there are only fed the lines of an extra discoupled 5 Volts supply. The I^2C buses and their periphery components have an own 5 Volts supply.

Outside the controller core, there is an EEPROM of 256 byte at the I^2C bus 1 which stores the front panel key settings.

The sound generator consists of the following functional sections:

- Quartz oscillator
- Programmable counter
- Activation switch
- Amplifier with level setting
- Controller interface

An oscillator with a consecutive programmable counter generates a sound frequency which can be set within an interval of two octaves corresponding to a section of a harmonic series. Setting is performed by the I^2C bus expander Z15 with a resolution of 7 bits, i. e. 128 different tones can be generated. The sound generator can be activated direct by the control signals HM and HB or by the controller via the bus expander. On activation by the controller the loudness will be set to maximum simultaneous.

A driver matches the output signal of the frequency counter to the connected sound transducer and enables variation of the output level.

The auxiliar power supply consists of the functional sections as follows:

- Rectifier
- Generation of +15 Volts
- Generation of +5 Volts for the controller core
- Generation of +5 Volts for the I^2C buses and the LED displays

From an unregulated DC voltage, the supply voltages +15 V and +IIC are gained by means of two monolithic integrated switch mode voltage regulators. The +15 V is splitted into the voltages +15M for auxiliar supply of the monopolar RF generator PCB, +15B for auxiliar supply of the bipolar RF generator PCB and +15H for supply of the RF output and the front PCBs. Additional, the extra supply voltage +5 V for the controller core is gained from +15 V by means of a linear voltage regulator.

The voltage +IIC supplies the interface components of both I^2C buses, additional the voltage +5D for supplying the LED displays at the front PCB is derived from this.

1.6.7 Standby PCB

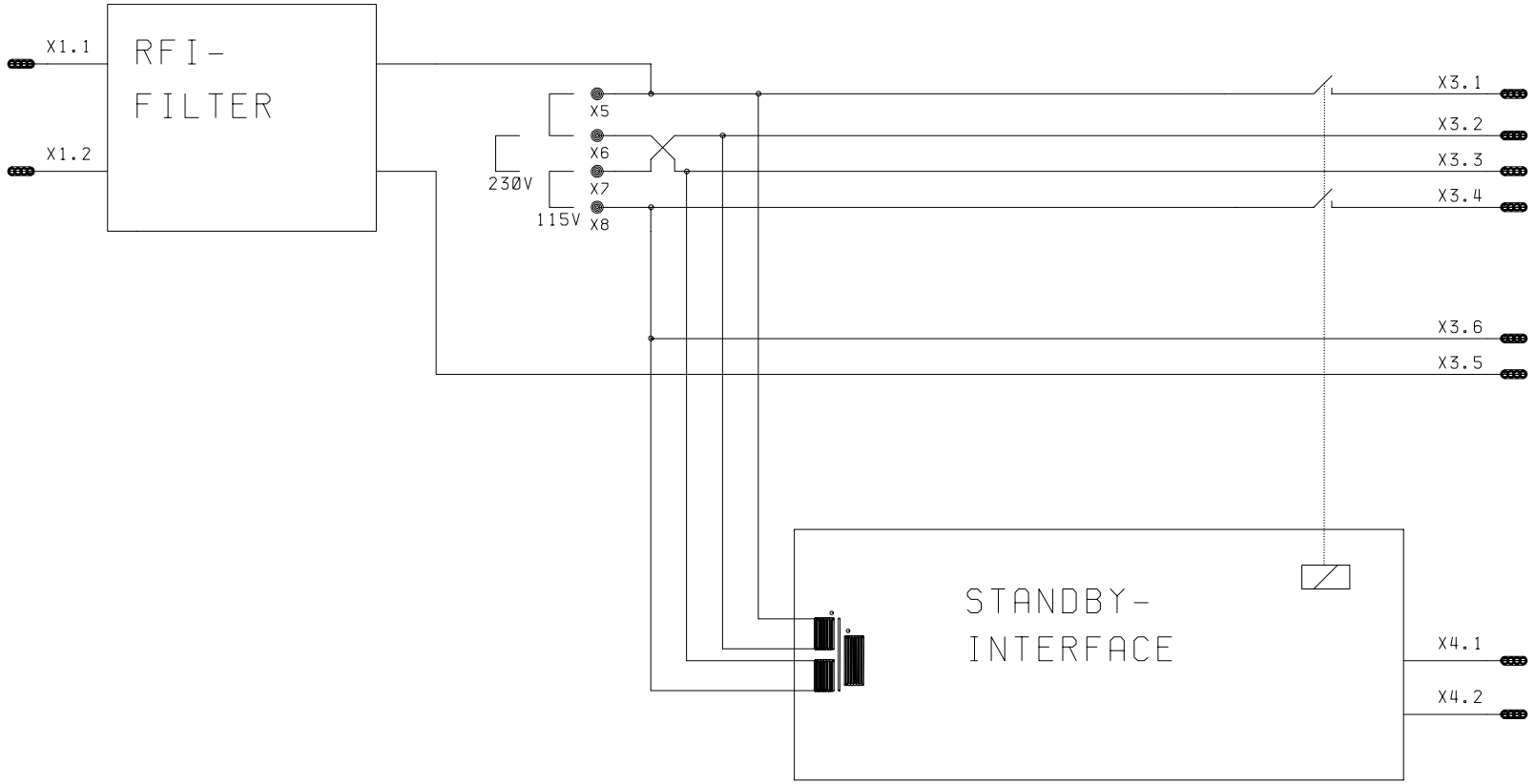
The interface to the mains power supply consists of the functional sections as follows:

- Mains relay with standby interface
- Voltage selection
- RFI filter

The mains relay is controlled by a bistable relay which is pulse controlled as a toggle mode switch. This circuit is supplied from a small auxiliar transformer.

Voltage interchange 115 Volts/230 Volts is performed by jumper soldering which simultaneous changes the auxiliar transformer. For matching to extraordinary voltages as 100 Volts (Japan), 127 Volts (Mexico) or 240 Volts (United Kingdom), an auxiliar winding on the primary of the main transformer has to be wired in serial or counterserial to the main winding.

The RFI filter consists of a X-type capacitor and a current compensated choke.



BLOCKDIAGRAM

STANDBY PCB A6 ME 401

FILE: 401US-4B.DIA

2. Disassembling and Reassembling of Components

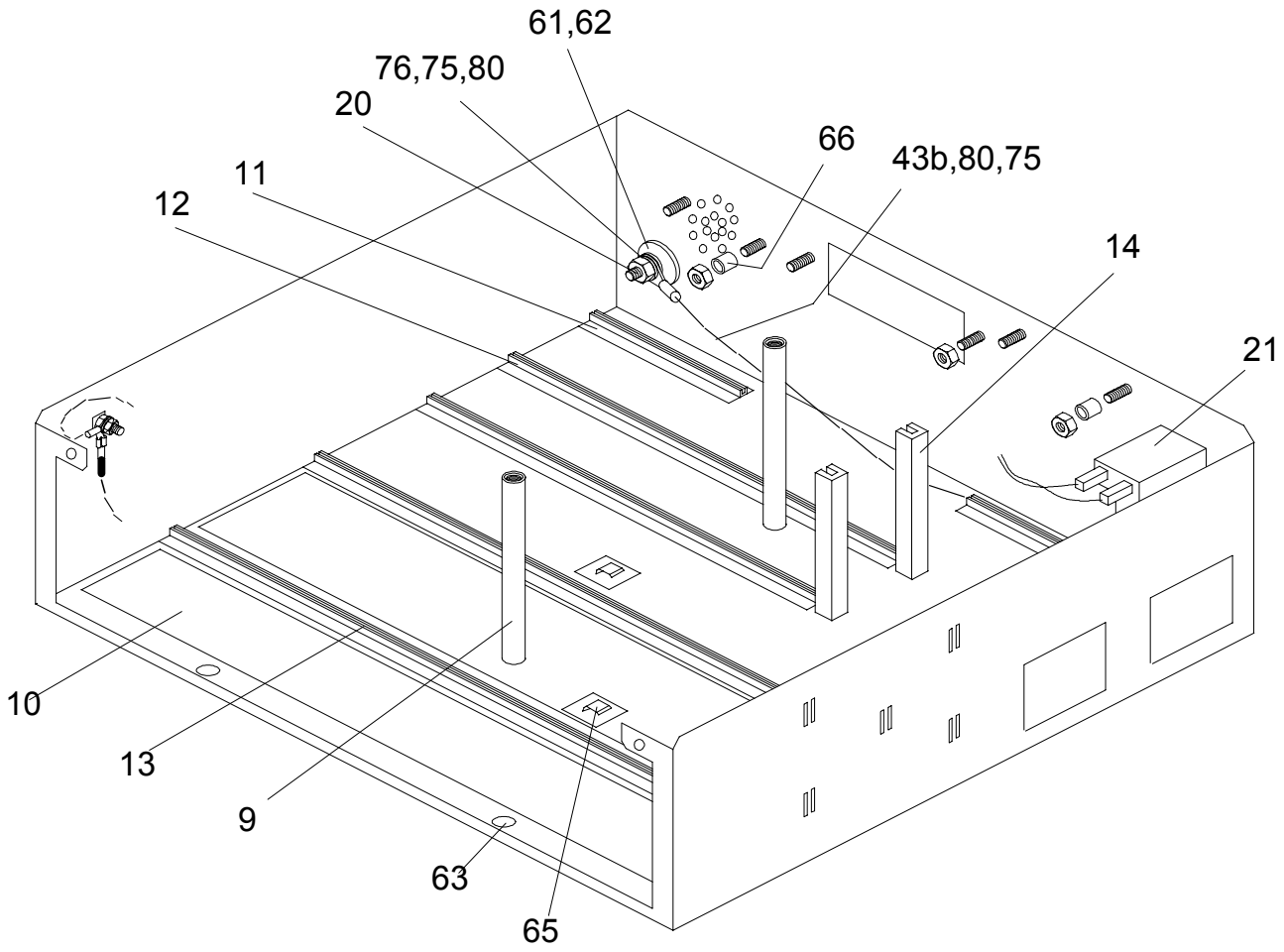
2.1 Components and Mechanical Parts ME 401

Pos.	Designation	Ordering No.
1	Top Cover	08-012-00-25
3	Front Panel	08-010-00-25
4	Front Layout Set HW State 01 (to Serial End No. 0059)*	08-010-00-30
	Front Layout Set HW State 02 to 05 (End No. 0060 to 0592)*	08-010-00-26
	Front Layout Set from HW State 06 (from Serial End No. 0593)*	08-010-00-34
5	Rotary Knob D30	08-006-00-01
6	Plastic Handle	08-032-00-02
7	Cover for Handle	08-001-00-15
8	Top Board Holder	08-014-00-15
9	Fastening Pin for Board Holder	08-032-00-10
10	Adhesive Base Insulation	08-003-00-08
11	Adhesive Board Fixing Bar 90 Millimeters	08-018-00-24
12	Adhesive Board Fixing Bar 225 Millimeters	08-018-00-18
13	Adhesive Board Fixing Bar 370 Millimeters	08-018-00-19
	Ground Fixing Bar for Monopolar PCB A8 (from End No. 0385)*	08-003-00-11
14	Vertical Board Fixing	08-020-00-14
	Base Casing, Pre-Assembled up to HW 03 (up to End No 0384)*	08-012-00-27
	Base Casing, Pre-Assembled from HW 04 (from End No. 0385)*	08-012-00-29
20	Equipotential Connector Pin up to HW 03 (up to End No. 0384)*	08-027-00-13
	Equipot. Connector Socket from HW 04 (from End No. 0385)*	08-027-00-14
21	Mains Terminal Bank	08-024-00-06
22	Drawer for Fuses	08-024-00-18
23	Mains Transformer PM 114	08-024-00-27
30	Sound Transducer Set cpl.	08-020-00-15
31	Setpoint Potentiometer cpl.	08-032-00-11
32	Socket Neutral Electrode cpl. with Insulation Cup	08-024-00-34
34	Socket Active Electrode cpl.	08-022-00-14
35	Socket for Foot Swtch Monopolar cpl.	08-010-00-27
36	Mounting Plate for Foot Switch Socket	08-001-00-16
37	Socket for Bipolar Output cpl.	08-003-00-06
38	Socket for Foot Switch Bipolar cpl.	08-010-00-28
40	Cable for Bus 26 Lines	08-003-00-07
41	Cable Set Mains Circuit	08-018-00-21
42	Cable Set Standby Circuit	08-018-00-20
43	Cable Set PE/Equipotential Lines	08-018-00-22
50	Front PCB A1, HW State 01 (up to Serial End No. 0059)*	08-010-00-31
	Front PCB A1 from HW State 02 (from Serial End No. 0060)*	08-010-00-29
51	RF Output PCB A2 (up to HW State 03, up to End No. 0384)*	08-014-00-18
	RF Output PCB A7 (from HW State 04, from End No. 0385)*	08-014-00-19
52	RF Generator PCB Monopolar A3 (up to HW 03, End No. 0384)*	08-014-00-17
	RF Generator PCB Monopolar A8 (from HW 04, End No. 0385)*	08-014-00-20
53	RF Generator PCB Bipolar A4	08-014-00-16
54	Controller PCB A5	08-022-00-15
55	Standby PCB A6	08-032-00-12

*) For detailed information, see item 5.

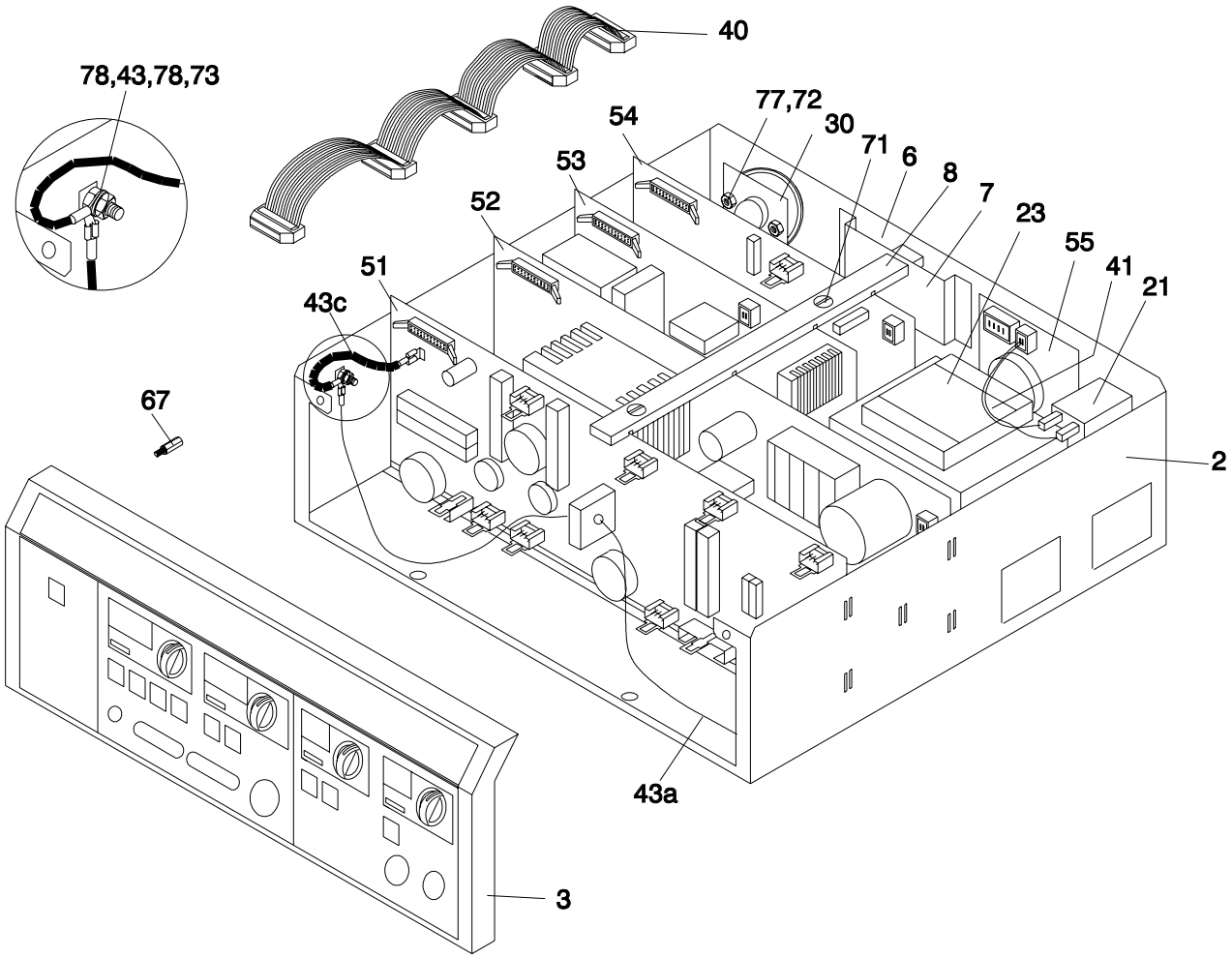
Pos.	Designation	Ordering No.
*	Set of Mechanical Parts ME 401	08-018-00-23
60	Case Stand, Adhesive (up to HW State 03, up to End No. 0384)*	
	Case Stand, Hole-Mounted (from HW 04, from End No. 0385)*	
61	Insulation Bushing for Equipotential Pin (up to HW State 03)*	
62	Insulation Washer for Eqipotential Pin (up to HW State 03)*	
63	Insulation Feedthrough for Bottom Receptacles (up to HW State 03)*	
	Insulated Clamp for Bottom Receptacles (from HW State 04)*	
64	Flat Connector PE Terminal 4.8 X 0.8mm	
65	Adhesive Cable Clip for Bipolar Output	
66	Spacer 6/3.5 X 10mm, Plastic	
67	Threaded Bolt M4 X 15mm	
68	Tallow-Drop Self-Tapping Screw 3.5 X 9.5mm	
69	Self-Tapping Screw 2.9 X 9.5mm	
70	Philips Tallow-Drop Screw M3 X 6mm	
71	Countersunk Screw M4 X 16mm	
72	Hexagonal Nut M3	
73	Hexagonal Nut M4	
74	Hexagonal Nut M5	
75	Hexagonal Nut M6	
76	Washer 6.4 X 12mm	
77	Lock Washer S3	
78	Lock Washer S4	
79	Lock Washer S5	
80	Lock Washer S6	
	Set of Adhesive Labels for ME Units	08-018-00-02
	Incandescant Bulb for Front PCB	08-012-00-03
	Fuse T4A Slow Blow (230V)	08-034-00-15
	Fuse T8A Slow Blow (115V)	08-034-00-14
	Fuse M1.6A Medium Blow (Controller PCB)	08-034-00-28
	Fuse M3.15A Medium Blow (Bipolar PCB)	08-034-00-29
	Fuse M10A Medium Blow (Monopolar PCB)	08-034-00-16
	<u>For units with Serial End No. up to 401 01 03 94 0059:</u>	
	EPROM Set with Opcode Version 1.06M/S3.03 (SW 03)*	08-008-00-15
	<u>For units with Serial End No. from 401 02 04 94 0060 up to 401 02 04 95 0384:</u>	
	EPROM Set with Opcode Version 2.01M/S3.04 (SW 04)*	08-008-00-12
	<u>For units from Serial End No. 401 04 06 95 0385:</u>	
	EPROM Set with Opcode Version 3.01M/S4.03 (SW 06)*	08-008-00-13
	EPROM Set with Opcode Version 3.01M/S4.04 (SW 07)*	-
	EPROM Set with Opcode Version 3.01M/S5.00 (SW 08)*	-
	EPROM Set with Opcode Version 3.01M/S4.05 (SW 10)*	08-008-00-16
	<u>For units with Serial No. 401 09 08 97 1051 up to 401 09 08 97 1063:</u>	
	EPROM Set with Opcode Version 3.01M/S5.00 (SW 08)*	-
	EPROM Set with Opcode Version 3.01M/S5.03 (SW 09)*	08-008-00-17
	RF Output PCB A9 (for HW 09)*	08-014-00-23
	RF Generator PCB Monopolar A10 (for HW 09)	08-014-00-22

*) For detailed information, see item 5.



ME401 ASSEMBLY OF BOTTOM CASE

File: 401BAUU.DRW



ME 401 BOARD ASSEMBLY

2.2 Opening and Closing of Case

1. Unplug mains cord.

2. Release the four self-tapping screws (69) at the rim at the rear side of the top cover (1).

3. Draw top cover (1) off of the groove in the front panel (3) and take it off over the backside of the unit.

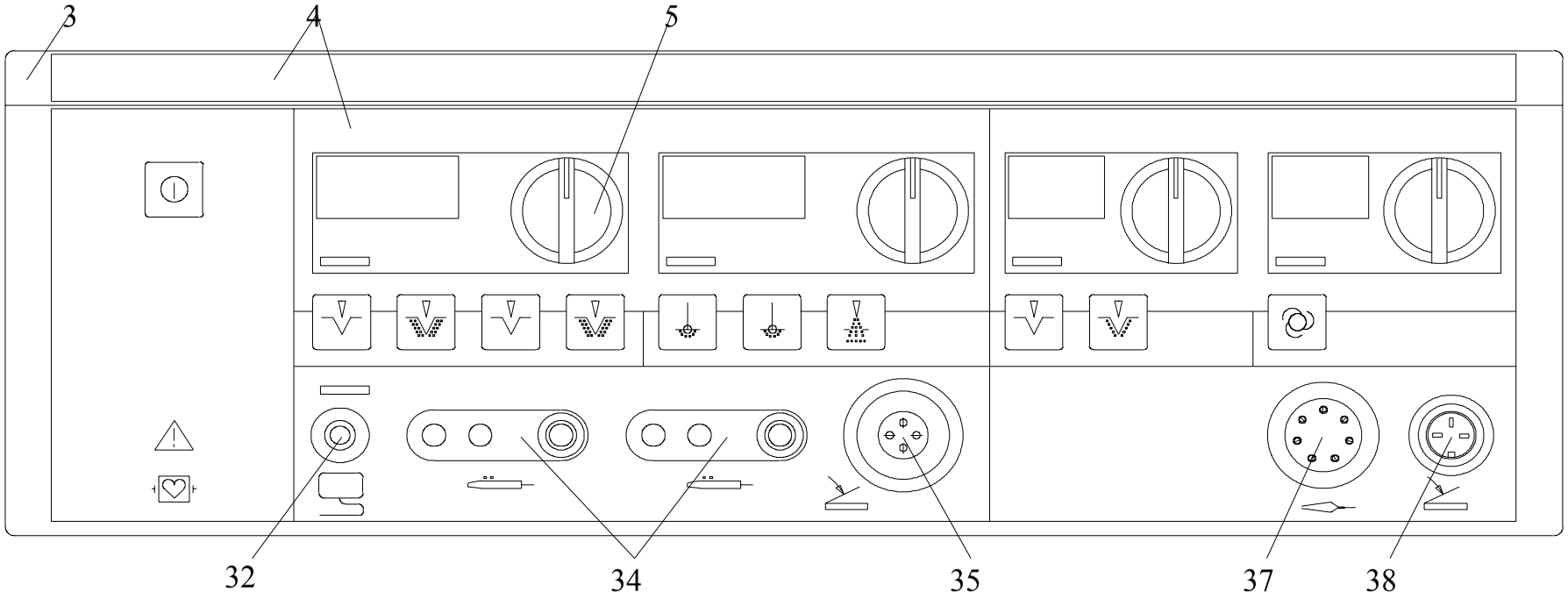
4. For reassembling push top cover (1) from the backside of the base casing (2). Take care of guiding the top cover correct into the groove in the front panel (3), especially at the sides.

5. Push top cover complete onto the rear side of base casing (2) and fix with self-tapping screws (69). Don't pull cover forward with the screws, else the rim may be bended. Check the unit for standing on all four stands without distorsion on a smooth surface else remove distorsion by releasing and retightening the screws.

2.3 Front Panel, Sockets, Potentiometer

2.3.1 Exchange of Setpoint Potentiometer (31)

1. Open unit according to 2.2.
2. Pull off rotary knob in axial direction (use pliers with cloth).
3. Release cable connection from RF output PCB.
4. Remove nut with socket wrench or pliers and remove potentiometer from the rear.
5. Insert replacement from the rear with the cable terminals to the right. On tightening the nut keep the potentiometer held counterwise else the settings may get a clockwise offset.
6. Replace rotary knob. If the knob cannot be turned free, the potentiometer is not centered well. Release nut for better centering.
7. Rearrange cable connection to RF output PCB.
8. Perform functional check according to 4.1.5.
9. Close case according to 2.2.



FRONTPANEL FRONT VIEW

2.3.2 Replacement of Sockets and Associated Parts (32-38)

1. Open unit according to 2.2.

2. Release cable connections X8-X11 of setpoint potentiometers at the RF output PCB and bus connector X1 at the front PCB.

3. Release bolts (67) on the left and the right of the front panel inner side.

4. Release cable connections X4 of the neutral electrode socket (32), X5 and X6 of the active electrode sockets and X7 of the bipolar socket at the bottom side of the RF output PCB. Remove front panel. For removing of foot switch sockets (35, 39), release cable connection from front PCB A1.

5. Unscrew and replace faulty socket. Take care of correct mounting position. Do not grip the NE socket (32) at the contact spring but at the front at the flange. With the foot switch sockets (35, 38), rearrange cable connection at the front PCB.

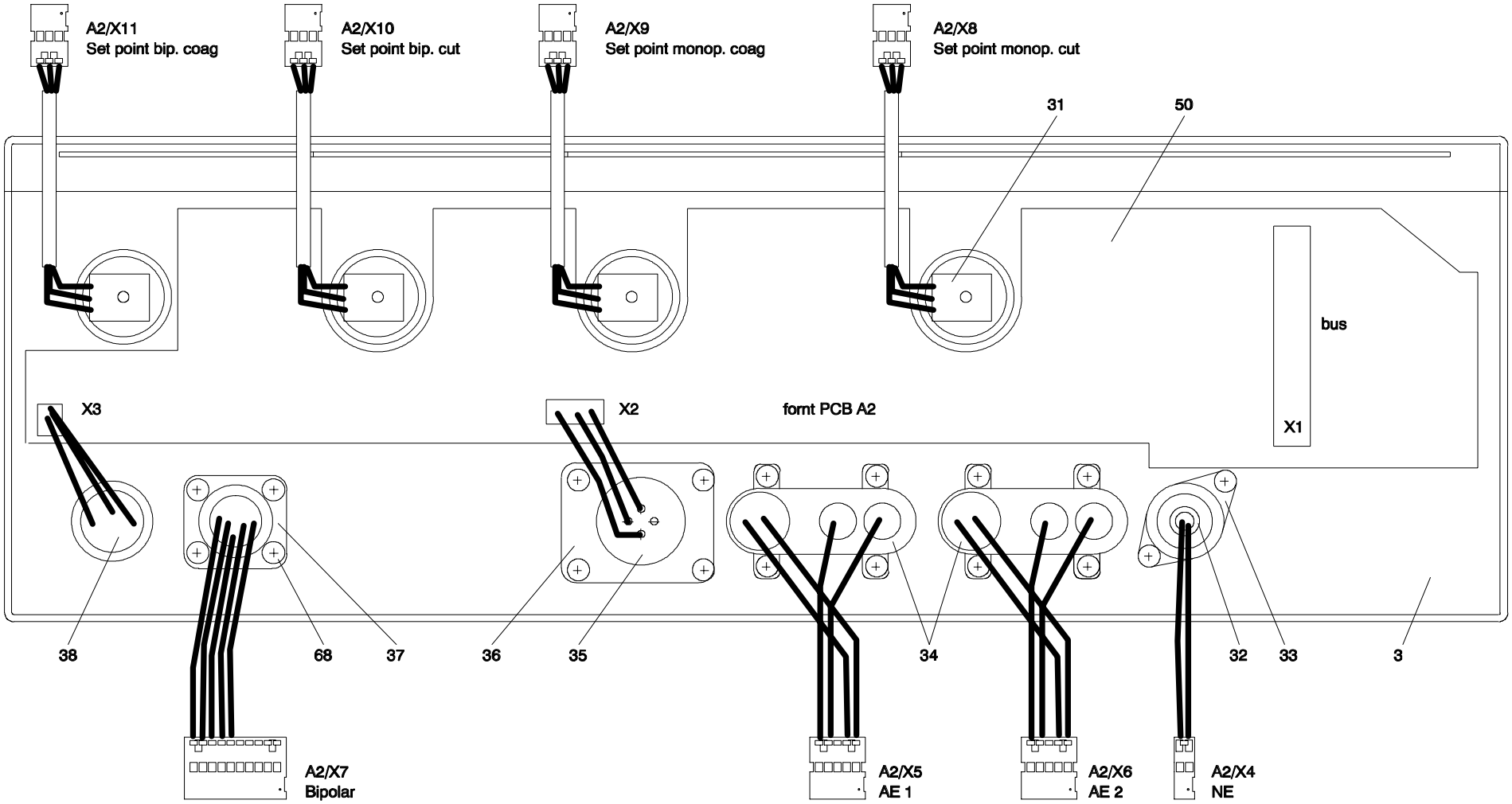
6. For reassembling rearrange cable connections X4, X5, X6 and X7 at the bottom side of the RF output PCB and hang front panel on the front edge of the case base.

7. Place and tighten bolts (67) at the upper left and upper right.

8. Plug cable connectors of the setpoint potentiometers into the sockets X8-X11 at the RF output PCB and rearrange bus cable connection X1 at the front PCB.

9. Perform functional and safety check according to 4.1.2 to 4.1.5.

10. Close unit according to 2.2.



FRONTPANEL REAR VIEW: location and connection of components

File: 401FTRLLDRW

2.3.3 Disassembling and Reassembling of Front PCB A1 (50)

1. Remove front panel accoding to 2.3.2 items 1 to 4.

2. Release cable connections X2 and X3 of the foot switch sockets at the rear of the board.

3. Carefully bend away the snap-in tongues of the front panel and lift board. Bend board off of front panel until it can be pulled out of the clamps at the lower edge.

4. For reassembling push lower edge of the board under the clamps at the rear of the front panel and latch it by slightly bending away the snap-in tongues.

5. Rearrange cable connections X2 and X3 of foot switch sockets.

6. Reassamble front panel according to 2.3.2 items 6 to 8.

7. Perform functional and safety check according to 4.1.2 to 4.1.5.

8. Close unit according to 2.2.

2.4 Disassembling and Reassembling of RF Output PCB A2 (up to HW State 03) or A7 (from HW State 04) (51)

1. Open unit according to 2.2.

2. Release countersunk screws (71) and remove top board holder (8).

3. Disconnect bus cable (40) from front PCB A1 (50) and RF output PCB A2 or A7 (51). Bend cable backwards.

4. Release plug X2 of the monopolar output transformer at the left rear of the board. To perform this, lift plug off of the board surface by bending and pull simultaneous to the left.

5. Unplug cable connections X8 to X11 of the setpoint potentiometers at the top side of the board.

6. Unplug PE conductor cable (43a) from the case terminal (64) at the front left and pull it out of the current transformer at the RF output board. Unplug guarding conductor from terminal X16.

7. Lift board and release cable connections of RF sockets X4 to X7 as well as bipolar output cable connection X3 at the lower edge of the board. Remove board.

8. For reassembling, place board into the guiding slots (up to HW state) or the between the guiding pins (from HW state 04) at the side parts of the case base (bus connector at the left top) and rearrange cable connections X3 to X7 at the lower edge of the board. Then press board into the groove of the fixing bar. Take care of correct feedthrough of the bipolar output cable and the PE conductor cable (43a).

Attention! Use only RF output PCB A2 (C 40-1295, ordering code 08-014-00-18) for hardware states up to 03 (up to serial end number 0384), use only RF output PCB A7 (C 40-1427, ordering code 08-014-00-19) for for hardware states from 04 (from serial end number 0385)!

9. Feed PE conductor cable (43a) through the hole of the current transformer and connect it to the terminal (64) at the front left inside of the case. Connect guarding line to terminal X16.

10. Rearrange connection to the monopolar RF output transformer at the rear left of the board.

11. Rearrange bus cable connection at the RF output and front PCBs.

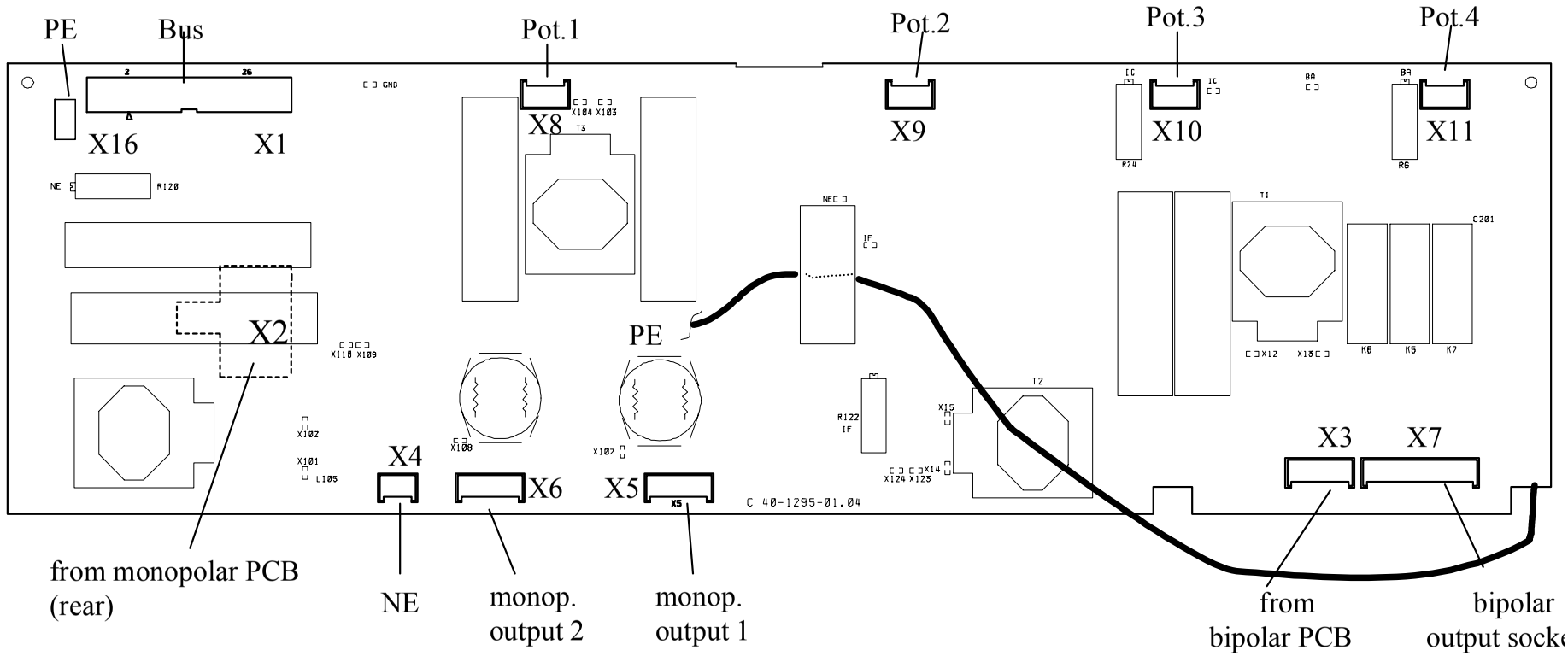
12. Rearrange cable connections X8 to X11of the setpoint potentiometers at the top side of the board.

13. Place top board holder (8) in handle cover (7) and tighten.

14. Perform alignments according to section 4.1.6.1.

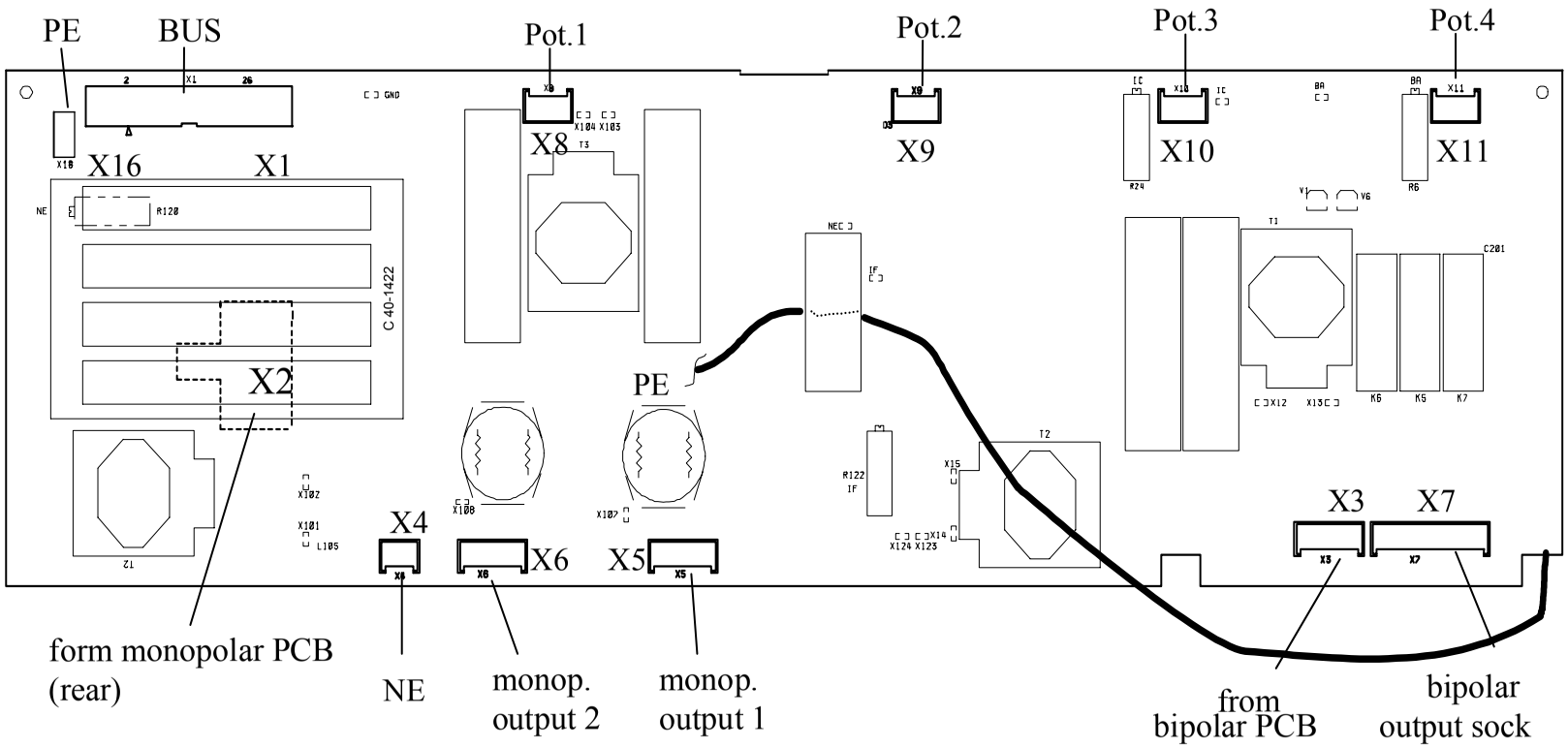
15. Perform functional and safety check according to 4.1.2 to 4.1.5.

16. Close case according to 2.2.



Connection of RF output PCB A2

File: DES1U.DRW



CONNECTION OF RF OUTPUT PCB A7

File: DES1BE.DRW

2.5 Disassembling and Reassembling of Monopolar RF Generator PCB A3 (up to HW State 03) or A8 (from HW State 04) (52)

1. Open unit according to 2.2.

2. Release countersunk screws (71) and remove top board holder (8).

3. Disconnect bus cable from controller board A5 (54), bipolar RF generator board A4 (53) and monopolar RF generator board A3 or A8 (52). Bend cable to the front side.

4. Release connector X2 of the output transformer at the left rear of the RF output board A2 or A7 (51). To perform this bend connector slightly off of the board surface and pull to the left simultaneous.

5. Release connector X2 from the mains transformer (23) and get connection cable out of the gap in the board.

6. Remove board unit topwards.

7. For reassembling place board unit in the grooves (up to hareware state 03) or between the guiding pins (from hardware state 04) at the case walls with basic and reinforcement board and press into the groove of the fixing bar at the bottom. Take care of proper position of the PE line cable and the bipolar output cable in the gaps in the lower board edge.

Attention! For HW states up to 03 (up to serial end number 0384), use only monopolar RF generator PCB A3 (C 40-1296, ordering code 08-014-00-17), for HW states from 04 (from serial number 0385), use only monopolar RF generator PCB A8 (C 40-1428, ordering code 08-014-00-20)!

8. Rearrange connection of the RF output transformer to the left rear of the RF output board A2 or A7.

9. Place the mains transformer cable in the keyhole shaped gap right in the upper edge and rearrange cable connection X4.

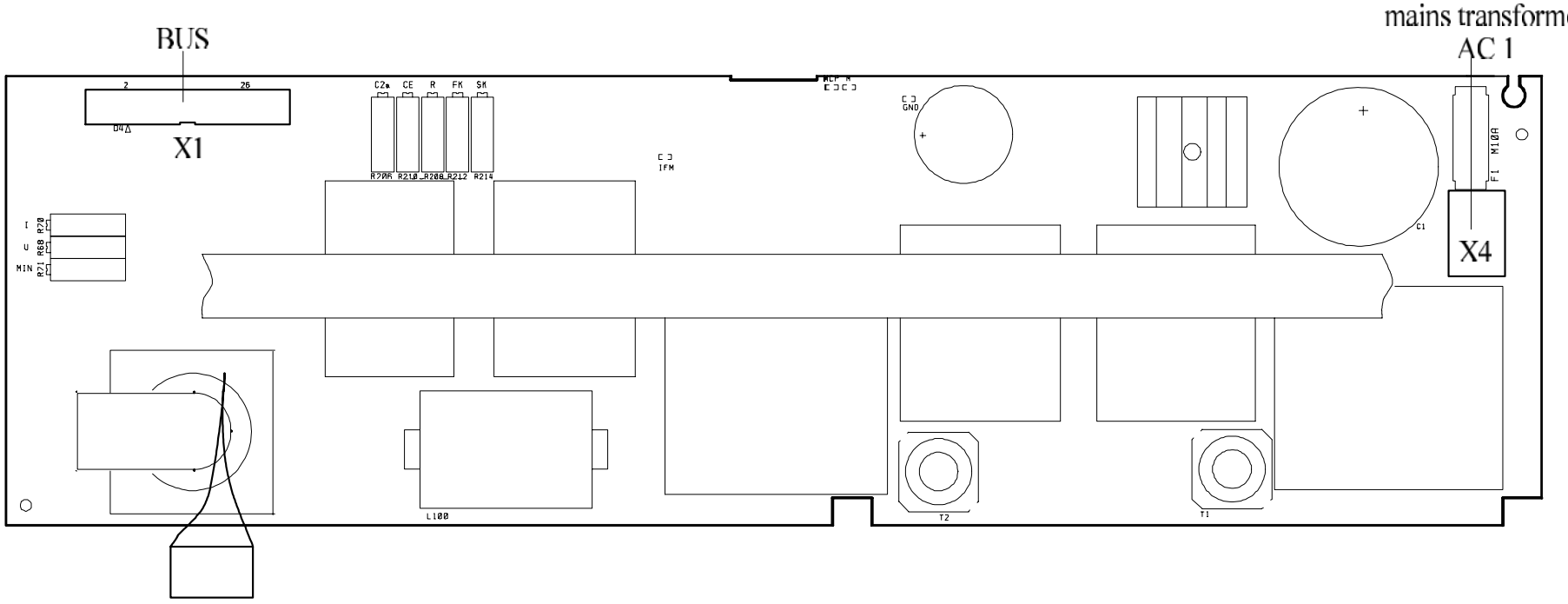
10. Rearrange bus cable connection to monopolar RF generator PCB A3 or A8, bipolar RF generator PCB A4 and controller PCB A5.

11. Place top board holder (8) and screw on.

12. Perform alignments according to 4.1.6.2.

13. Perform functional and safety checks according to 4.1.3 and 4.1.4.

14. Close case according to 2.2.



CONNECTION OF MONOPOLAR RF GENERATOR A3/A8

File: DES3BE.DRW

2.6 Disassembling and Reassembling of Bipolar RF Generator PCB A4 (53)

1. Open unit according to 2.2.

2. Release countersunk screw (71) and remove top board holder (8).

3. Disconnect bus cable (40) from controller board A5, bipolar board A4, monopolar board A3 and RF output board A2.

4. Disassemble monopolar board A3 (52) according to 2.5.

5. Release the cable connection X3 of the bipolar output cable from the right front of the lower edge of the RF output board A2. Lift output board slightly and pull cable from under the board and take it out of the cable clamps (65) at the bottom.

6. Release cable connections X2 from the mains transformer (23) and X5 of the standby PCB connection cable (42). Remove bipolar board.

7. For reassembling place bipolar board A4 in the grooves between vertical board fixing (14) and left case wall and press it into the groove of the fixing bar at the bottom. Place output cable into the cable clips (65) at the bottom. Guide cable with connector under the RF output board and rearrange connection X3. Press RF output board back into the fixing bar at the bottom. Take care that the bipolar output cable is placed correct in the gap in the lower edge of the board and will not be jammed.

8. Rearrange connections X2 of the mains transformer cable and X5 of the standby PCB connection cable (42). Take care that the connection cable (42) is plugged tight at both ends.

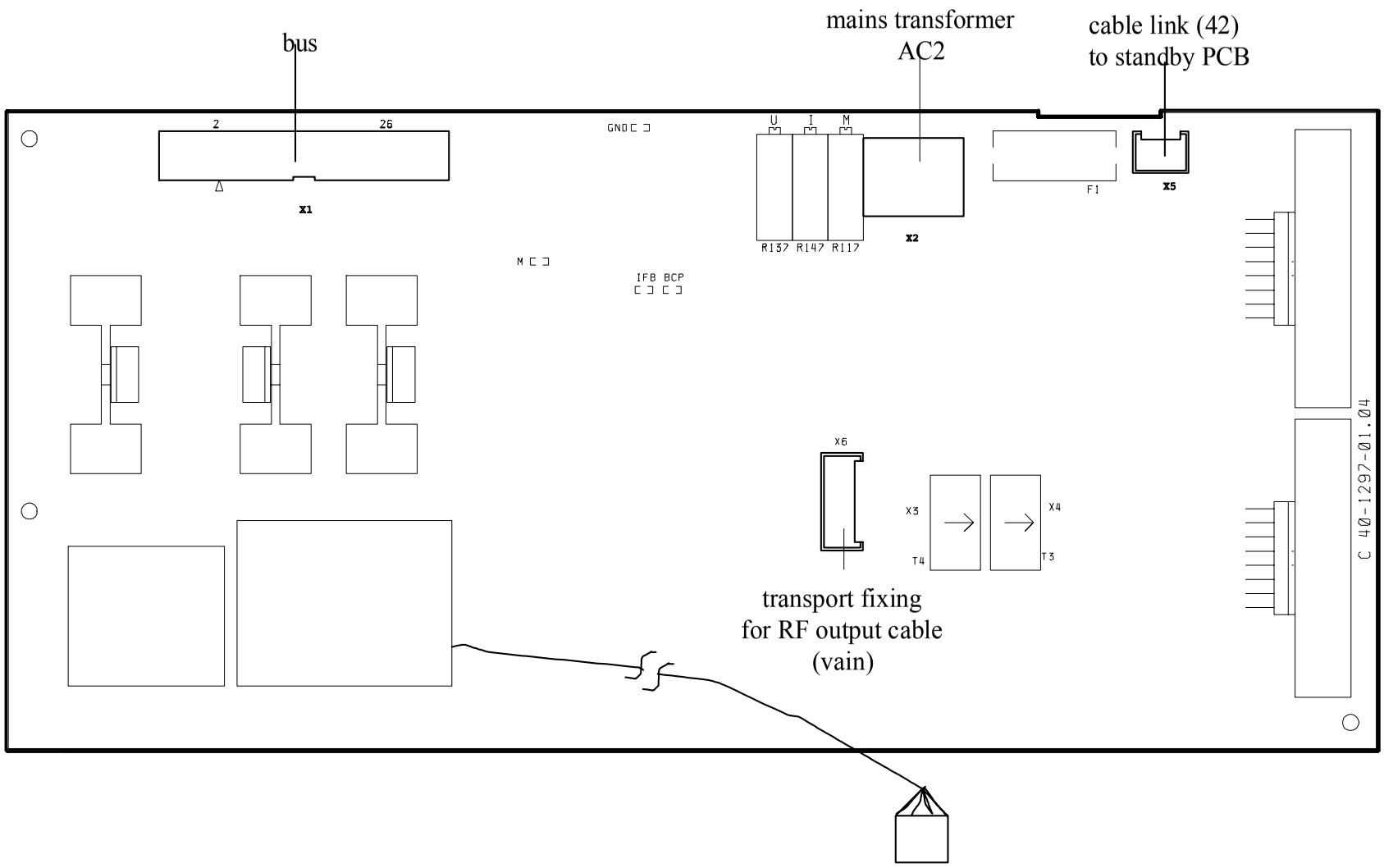
9. Reassemble monopolar board A3 (52) according to 2.5. Rearrange bus cable connection.

10. Place top board holder (8) and screw on.

11. Perform alignments according to 4.1.6.3.

12. Perform functional and safety checks according to 4.1.3 and 4.1.4.

13. Close case according to 2.2



Connection of bipolar RF generator PCB A4

2.7 Disassembling and Reassembling of Controller PCB A5 (54)

1. Open unit according to 2.2.

2. Release countersunk screws (71) and remove top board holder (8).

3. Release cable connections X1 of bus cable (40) and X7 of mains transformer (23). Release cable connection of sound transducer and take cable out of the keyhole shaped gap at the left of the board. Remove board.

4. In case of assembling a new board, check for correct software installation according to 5.4 and correct DIL switch settings according to 4.3.

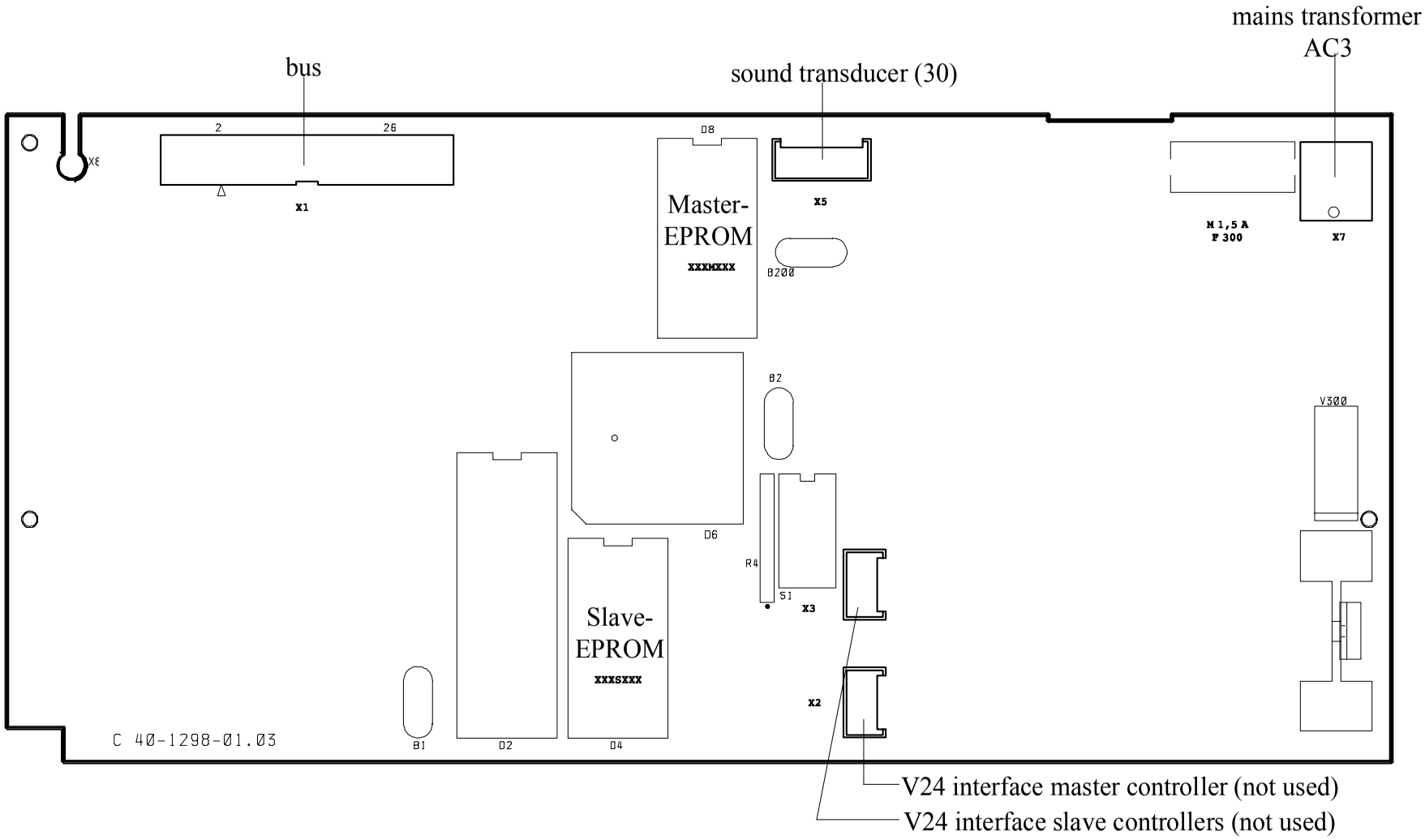
5. For reassembling place board into the grooves of the vertical board fixing (14) and the case wall and press into the groove in the fixing bar at the ground.

6. Place cable of the sound transducer set (30) into the keyhole shaped gap at the left of the board and rearrange connection X5.

7. Connect bus cable (40) to X1 and mains transformer cable to X7.

8. Perform functional and safety checks according to 4.1.4 and 4.1.5.

9. Close case according to 2.2.



Connection of controller PCB A5

File: DES7U.DRW

2.8 Disassembling and Reassembling of Standby PCB A6 (59)

1. Open case according to 2.2.

2. Release cable connections X3 from the mains transformer (23) and X1 of the mains circuit cable (41).

3. Release cable connection X4 of standby circuit cable (42) from the bipolar board.

4. Release nuts (72) and remove board.

5. In case of assembling a new board check for proper mains voltage setting of the jumpers at X5 to X8 according to 4.2.

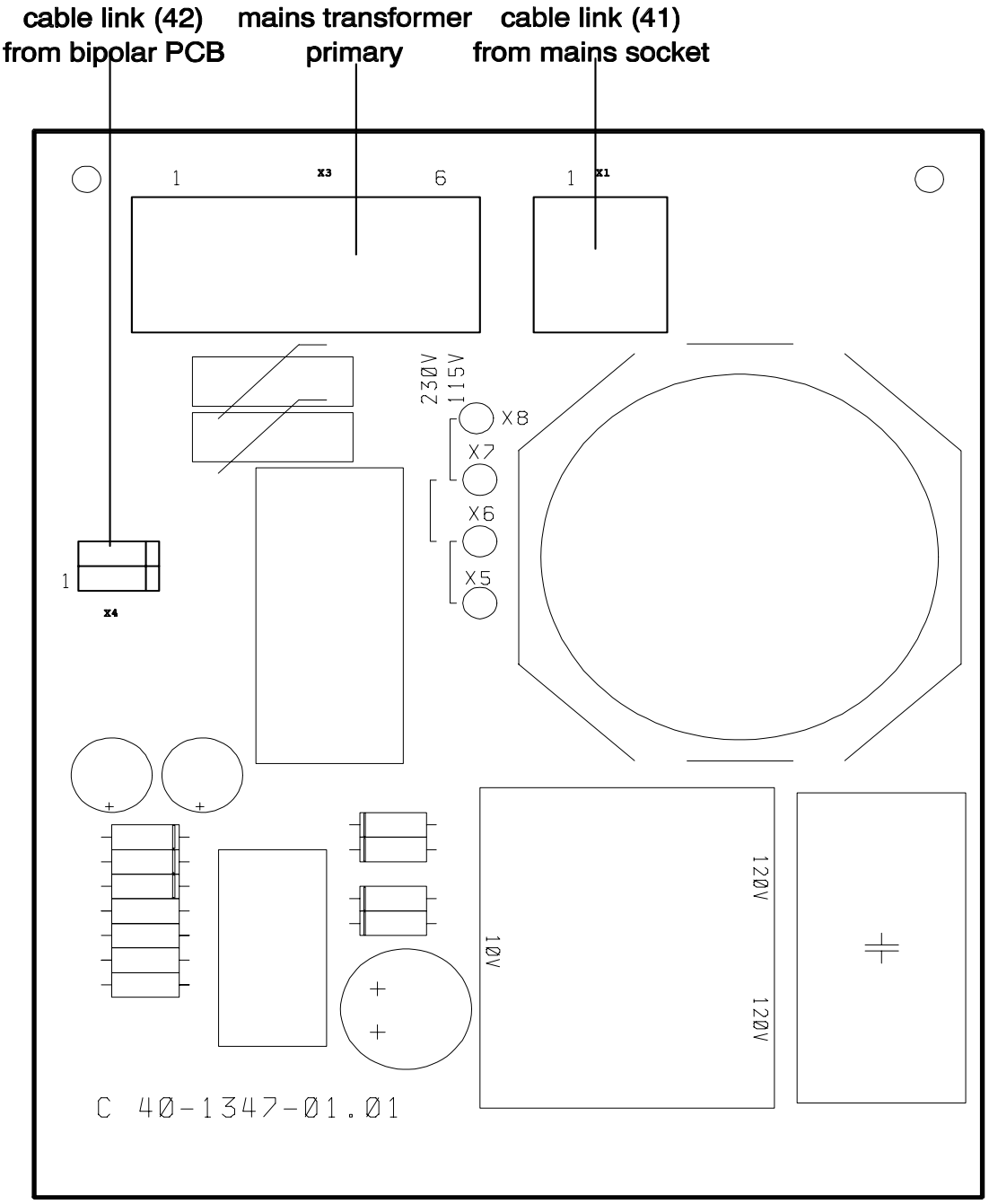
6. For reassembling place board into the groove of the fixing bar at the bottom and swing it onto the stud bolts. Take care of presence of spacers (66) on both sides. Tighten with nuts (72) and lock washers (77).

7. Plug in the connector of the standby circuit connection cable (42) from the bipolar board. Take care for the other end to be plugged properly at the bipolar board A4 (93).

8. Plug in cable connector X3 of the mains transformer and cable connector X1 of the mains circuit connector (41).

9. Perform functional and safety checks according to 4.1.3 and 4.1.4.

10. Close case according to 2.2.



Connection of standby PCB A6

File: DES9U.DRW

2.9 Disassembling and Reassembling of Mains Transformer (23)

1. Open unit according to 2.2.

2. Release countersunk screws (71) and remove top board holder (8).

3. Disassemble controller board according to 2.7.

4. At the bipolar board A4 (53), release cable connections X1 of the bus cable, X2 of the mains transformer and X5 of the standby circuit cable connector (42). Draw bipolar board upwards out of the fixings and lay board to the left side with the component side downwards.

5. Release cable connections of the mains transformer X4 at the monopolar board A3 (52) and X3 at the standby board A6 (55).

6. Remove mains circuit connection cable (41) between the mains connection set (21) and the standby board A6 (55).

7. Release nuts (74) at the case bottom and remove mains transformer.

8. For reassembling place transformer from above. Note that the six-polar primary connector is directed to the backside and that the PE line cable at the right edge of the case bottom will not be jammed. Mount transformer with washers (76), lock washers (79) and nuts (74). Prior to that, the transformer is probably to be matched to a different mains voltage according to item 4.2.

9. Reassemble bipolar board A4 (53) according to 2.6.

10. Reassemble controller board A5 (54) according to 2.7.

11. Rearrange cable connection X4 from the transformer at the monopolar board A3 (52) and place cable into the keyhole shaped gap right in the board's edge. Rearrange cable connection X3 from the mains transformer at the standby board A6 (55).

12. Reassemble mains circuit connection cable (41) from mains connection set (21) to X1 of the standby board A6 (55).

13. Place top board holder (8) and mount with countersunk screws (71).

14. Perform functional and safety checks according to 4.1.2 to 4.1.5.

15. Close case according to 2.2.

2.10 Exchange of Mains Terminal Block (21)

1. Release self-tapping screws (69) at the terminal block and pull it off carefully. Eventually open case according to 2.2.

2. Release connectors from mains and PE terminals and plug to the new part.

3. Push new terminal block into the rear of the case and tighten with self-tapping screws (69).

4. Eventually place fuse drawer (22) with fuses from the old to the new part. Take care of correct fuse values.

5. Perform safety check according to 4.1.4.

6. Eventually close case according to 2.2.

Disassembling and Reassembling of Sound Transducer Set (30)

1. Open case according to 2.2.

2. Release cable connection X5 at the controller board A5 and take cable out of the keyhole shaped gap at left of the board.

3. Release nuts (72) and remove set.

4. For reassembling place transducer set (30) into the groove of the fixing bar (11) at the bottom and swing it onto the stud bolts. Take care of the presence of the spacers (66). Tighten with lock washers (77) and nuts (72).

5. Place cable into the keyhole shaped gap at the left of the controller board A5, guide it under the bus cable (40) and rearrange cable connection X5 at the controller board.

6. Perform functional check according to 4.1.5.

7. Close case according to 2.2.

3. Fault Diagnosis

For changing a faulty component, this has to be identified at first. There are faults which can be recognized by the unit itself and such which require an external investigation.

The ME 401 supports a fault diagnosis by means of its microcontrollers. At that the controller checks itself and its periphery for operation and the input data for correctness of values. In case of disagreement, if the controller is able to perform, a coded error message will be displayed at the front panel by which the letters "Err" will be displayed in the monopolar cut section and an error code number will be displayed in the monopolar coagulation section. In most cases the error code number enables a direct conclusion for the faulty component.

Such errors which cannot be recognized by the unit itself can be associated with a certain component by a troubleshooting table in most cases.

In cases where the features offered here will not result in an undoubtly fault diagnosis with trouble shooting, please contact the MARTIN Service Center.

3.1 Error Codes and Their Meaning

Err 01

Meaning: The A/D converter Z1 (D6, PCF 8591) at the RF output PCB A2/A7 which transfers the analogue values of the setpoint potentiometers to the master controller cannot be initialized via I^2C bus.

Cause: Fault at or around this component.

Repair: Change of RF output board A2/A7 (51). If the fault is still there try change of controller PCB A5 (54) or bus cable (40).

Err 02

Meaning: The A/D converter Z2 (D5, PCF 8591) at the RF output board A2/A7 which transfers the analogue values of the setpoint potentiometers to the slave controller cannot be initialized. Or communication at the slave I^2C bus is blocked.

Cause: Fault at or around this component. Because this component will be initialized for first, the cause may also be a general failure at the RF output board A2/A7 or a incidental blocking of the slave I^2C bus caused by an other component at an other board.

Repair: First check cable connections X1 of the bus cable at the controller board A5 and the RF output board A2/A7. If this does not result in fault recognition, change RF output board A2/A7 (51). If the fault is still present then try change of controller board A5 (54) or bus cable (40).

Err 03

Meaning: The A/D converter Z3 (D6, PCF 8591) at the RF output board A2/A7 which transfers the analogue values of the monitoring functions to the master controller cannot be initialized.

Cause: Fault at or around this component.

Repair: Change RF output board A2/A7 (51). if the fault is still there, try provisional change of controller board A5 (54) or bus cable (40).

Err 04

Meaning: The I^2C expander Z4 (D3, PCF 8574) at the output board A2/A7 (51) which transfers the finger switch signals of the handpieces to the master controller cannot be initialized.

Cause: Fault at or around this component. Because this component is the first to be initialized at this board, a fault of the port units Z1, Z3 or Z5 may also be cause for this.

Repair: Change RF output board A2/A7 (51). If the fault is still there, try provisional change of controller board A5 (54) or bus cable (40).

Err 05

Meaning: The I^2C bus expander Z5 (D7, PCF 8574) at the output board A2/A7 by which the master controller controls the output relays cannot be initialized.

Cause: Fault at or around this component.

Repair: Change RF output board A2/A7 (51). If the fault is still there, try provisional change of controller board A5 (54) or bus cable (40).

Err 06

Meaning: The I^2C bus expander Z6 (D4, PCF 8574) at the front board A1 which transmits the front key and foot switch signals of the monopolar operation section to the master controller cannot be initialized.

Cause: Fault at or around this component.

Repair: Change of front board A1 (50) (by changing of the bus cable connection X1, a replacement board can be connected provisional prior to disassembling of the front part). If the fault is still there, try provisional change of controller board A5 (54) or bus cable (40).

Err 07

Meaning: The I2C bus expander Z7 (D5, PCF 8574) at the front board A1 which transfers the front key and foot switch signals of the bipolar operation section to the master controller cannot be initialized.

Cause: Fault at or around this component.

Repair: Change of front board A1 (50) (by changing of the bus cable connection X1, a replacement board can be connected provisional prior to disassembling of the front part). If the fault is still there, try provisional change of controller board A5 (54) or bus cable (40).

Err 13

Meaning: The A/D-D/A converter Z13 (D4, PCF 8591) at the monopolar RF generator board which transfers the analogue operation data to the slave controller and receives the compare setpoint value for the fault monitoring circuit cannot be initialized.

Cause: Fault at or around this component. Because this component is the first to be initialized by the slave I^2C bus at this board, a total failure of the board may be cause for this.

Repair: First check bus cable connection X1 at the monopolar RF generator board A3/A8 and at the controller board A5. If no fault can be found, change monopolar RF generator A3/A8 (52). If the fault is still there, try provisional change of controller board A5 (54) or bus cable (40).

Err 14

Meaning: The I^2C bus expander Z14 (D2, PCF 8574) at the monopolar RF generator board by which the slave controller controls the setting of the modulator, the operation mode and the activation of the RF generator cannot be initialized.

Cause: Fault at or around this component.

Repair: Change of monopolar RF generator board A3/A8 (52). If the fault is still there, try provisional change of controller board A5 (54) or bus cable (40).

Err 15

Meaning: The I^2C bus expander Z15 (D18, PCF 8574) at the controller board by which the slave controller sets the activation and frequency of the sound generator cannot be initialized.

Cause: Fault at or around this component.

Repair: Change controller board A5 (54).

Err 18

Meaning: The A/D-D/A converter Z18 (D1, PCF 8591) at the bipolar RF generator board which transfers the analogue operation data to the slave controller and receives the compare setpoint value for the fault monitoring circuit cannot be initialized.

Cause: Fault at or around this component. Because this component is the first to be initialized by the slave I^2C bus at this board, a total failure of the board may be cause for this.

Repair: First check bus cable connection X1 at the bipolar RF generator board A4 and at the controller board A5. If no fault can be found, change bipolar RF generator A4 (53). If the fault is still there, try provisional change of controller board A5 (54) or bus cable (40).

Err 19

Meaning: The I^2C bus expander Z19 (D2, PCF 8574) at the bipolar RF generator board by which the slave controller controls the setting of the modulator and the activation of the RF generator cannot be initialized.

Cause: Fault at or around this component.

Repair: Change of bipolar RF generator board A4 (53). If the fault is still there, try provisional change of controller board A5 (54) or bus cable (40).

Err 20

Meaning: The EEPROM Z20 (D10, PCF 8582) at the controller board where the master controller stores the current mode settings nonvolative cannot be initialized.

Cause: Fault at or around this component. Because the master controller checks this component at first at the power-on self test, the cause for this may also be a total failure of the master I^2C bus or a blocking of the master I^2C bus by an other faulty port unit placed at any other board.

Repair: Change controller board A5 (54). If the fault is still there, switch off the unit and disconnect successively the monopolar RF generator board A3/A8, the bipolar RF generator board A4 and the RF output board A2/A7 from the bus. If there will be displayed an other message than Err 20 after power-on, then change this board disconnected at last. If this procedure makes the fault not vanish, then change bus cable (40).

Err 21

Meaning: Fault in the circuit of the setpoint potentiometer (31) for power setting for monopolar cutting.

Cause: There is an interruption in the potentiometer lines or a fault at one of the A/D converters at the RF output board.

Repair: Connect spare part potentiometer (31) to the cable connection X8 at the RF output board A2/A7. If the fault is vanished, change potentiometer. If the fault is still there, change RF output board A2/A7 (51).

Err 22

Meaning: Fault in the circuit of the setpoint potentiometer (31) for power setting for monopolar coagulation.

Cause: There is an interruption in the potentiometer lines or a fault at one of the A/D converters at the RF output board.

Repair: Connect spare part potentiometer (31) to the cable connection X9 at the RF output board A2/A7. If the fault is vanished, change potentiometer. If the fault is still there, change RF output board A2/A7 (51).

Err 23

Meaning: Fault in the circuit of the setpoint potentiometer (31) for power setting for bipolar cutting.

Cause: There is an interruption in the potentiometer lines or a fault at one of the A/D converters at the RF output board.

Repair: Connect spare part potentiometer (31) to the cable connection X10 at the RF output board A2/A7. If the fault is vanished, change potentiometer. If the fault is still there, change RF output board A2/A7 (51).

Err 24

Meaning: Fault in the circuit of the setpoint potentiometer (31) for power setting for bipolar coagulation.

Cause: There is an interruption in the potentiometer lines or a fault at one of the A/D converters at the RF output board.

Repair: Connect spare part potentiometer (31) to the cable connection X11 at the RF output board A2/A7. If the fault is vanished, change potentiometer. If the fault is still there, change RF output board A2/A7 (51).

Err 25

Meaning: Faulty pre-regulated DC voltage of the monopolar RF generator A3/A8.

Cause: The pre-regulated voltage of the monopolar RF generator is either too high or too low. A voltage too high is caused by a serious fault of the powerelectronic stage of the monopolar RF generator or of its control. A voltage too low may be caused by the same circumstances, in the simplest case the fuse F1 (10A) is blown. In case of sporadic appearence, a mains voltage too low or with a short interruption may be the cause.

Repair: First the fuse F1 at the monopolar RF generator board should be checked for being blown. If it is not or it blows again immediately after power-on, then change monopolar RF generator board A3/A8 (52).

Err 26

Meaning: Faulty pre-regulated DC voltage of the bipolar RF generator A4.

Cause: The pre-regulated voltage of the bipolar RF generator is either too high or too low. A voltage too high is caused by a serious fault of the powerelectronic stage of the bipolar RF generator or of its control. A voltage too low may be caused by the same circumstances, in the simplest case the fuse F1 (3.15A) is blown. In case of sporadic appearence, a mains voltage too low or with a short interruption may be the cause.

Repair: First the fuse F1 at the bipolar RF generator board should be checked for being blown. If it is not or it blows again immediately after power-on, then change bipolar RF generator board A4 (53).

Err 27

Meaning: The ratio between the 15 Volts auxiliar supply and the reference voltage at the monopolar RF generator board is faulty.

Cause: Either the voltage of the auxiliar supply has changed or the reference voltage is increased.

Repair: Check 15 Volts of auxiliar supply. If this is correct, change monopolar RF generator board A3/A8 (52).

Err 28

Meaning: The ratio between the 15 Volts auxiliar supply and the reference voltage at the bipolar RF generator board is faulty.

Cause: Either the voltage of the auxiliar supply has changed or the reference voltage is increased.

Repair: Check 15 Volts of auxiliar supply. If this is correct, change bipolar RF generator board A4 (53).

Err 31

Meaning: The slave controller EPROM has changed its contence or cannot be read correct anymore.

Cause: Aging or spontaneous failure, probably caused by x-rays. Fault of the microcontroller bus system.

Repair: Change of both EPROMs. If the fault is still there, then change controller board A5 (54).

Err 32

Meaning: The master controller EPROM has changed its contence or cannot be read correct anymore.

Cause: Aging or spontaneous failure, probably caused by x-rays. Fault of the microcontroller bus system.

Repair: Change of both EPROMs. If the fault is still there, then change controller board A5 (54).

Err 37

Meaning: The SDA line of the I^2C bus 1 is blocked.

Cause: Fault of an interface component at the I^2C bus 1. If the fault occured during RF activation at high power setting, this may be a synchronisation fault caused by self induced electromagnetic interference. Then the error message vanishes after power-off and power-on again.

Repair: If the fault is still there after power-off and power-on, then the board with the faulty component must be localised by disconnecting the bus cable from the RF output board A2/A7 (51). If there is an other error message after power-off and power-on, then change RF output board A2/A7 (51). If it is unchanged, then the fault must be localised either at the front board A1 (50) or the controller board A5 (54).

Err 38

Meaning: The SDA line of the I^2C bus 2 is blocked.

Cause: Fault of an interface component at the I^2C bus 2. If the fault occured during RF activation at high power setting, this may be a synchronisation fault caused by self induced electromagnetic interference. Then the error message vanishes after power-off and power-on.

Repair: If the fault is still there after power-off and power-on, then the board with the faulty component must be localised by disconnecting the bus cable successively from the RF generator boards A3/A8 (52) and A4 (53) and the RF output board A2/A7 (51). If there is an other error message after power-off and power-on, then change the board which was disconnected at last. If it is unchanged, then the fault must be localised at the controller board A5 (54).

Err 40

Meaning: Triggering of the microcontroller watchdog.

Cause: Fault in the microcontroller system or synchronisation failure, short interruption of microcontroller power supply caused by a short interruption of the mains voltage or a decay of voltage due to shorted circuit.

Repair: If the unit won't operate normally after power-off and power-on, change controller PCB A5 (54) and observe the unit if operating again over a longer period of time under power load conditions. If the fault occurs again, then there may be a feedback effect on the auxiliar power supply caused by an other board. Observe +15V and find out faulty board by successively disconnecting of bus connectors.

If the message "Err 31" or "Err 32" occurs instead of "Err 40", then one of the EPROMs has changed its contence. In this case, both of the EPROMs have to be replaced.

Err 41, Err 42

Meaning: On the power-on self test, the unit recognizes an operation of the yellow or the blue finger switch of a handpiece connected to the right monopolar output.

Cause: Operation of a finger switch before end of power-on self test, short circuit at the handpiece or its connection cable or fault of the unit.

Repair: If not caused by switch operation, disconnect handpiece and switch off unit and switch on again. If the error message is still present, there is a fault at the RF output board A2/A7 (51). Probable cause at "Err 41": There was an attempt to draw RF power from one of the control sockets for the three pin US handpiece connectors with a 4 millimeters plug as is common with resectoscopes or the plug was pressed into the ring-shaped gap between inner and outer conductor of the coax socket. This may result in destroying of the capacitor C 107 at the RF output board. In areas where operation is performed preferential with such instruments (e. g. urology) we advise to close those control sockets with dummy plugs and to inform the users about this possibility of mishandling.

Err 43, Err 44

Meaning: On the power-on self test, the unit recognizes an operation of the yellow or the blue finger switch of a handpiece connected to the left monopolar output.

Cause: Operation of a finger switch before end of power-on self test, short circuit at the handpiece or its connection cable or fault of the unit.

Repair: If not caused by switch operation, disconnect handpiece and switch off unit and switch on again. If the error message is still present, there is a fault at the RF output board A2/A7 (51).

Err 45, Err 46

Meaning: On the power-on self test, the unit recognizes an operation of the finger switch for bipolar cutting or bipolar coagulation of an instrument connected to the bipolar output.

Cause: Operation of a finger switch before end of power-on self test, short circuit at the instrument or its connection cable or fault of the unit.

Repair: If not caused by switch operation, disconnect instrument and switch off unit and switch on again. If the error message is still present, there is a fault at the RF output board A2/A7 (51).

Err 47, Err 48

Meaning: On the power-on self test, the unit recognizes an operation of the yellow or the blue pedal of the monopolar foot switch.

Cause: Operation of the foot switch before end of power-on self test, short circuit at the foot switch or its connection cable or fault of the unit.

Repair: If not caused by switch operation, disconnect foot switch and switch off unit and switch on again. If the error message is still present, there is a fault at the front board A1 (50).

Err 49, Err 50

Meaning: On the power-on self test, the unit recognizes an activation of bipolar cutting or bipolar coagulation by the bipolar foot switch.

Cause: Operation of the foot switch before end of power-on self test, short circuit at the foot switch or its connection cable or fault of the unit.

Repair: If not caused by switch operation, disconnect foot switch and switch off unit and switch on again. If the error message is still present, there is a fault at the front board A1 (50).

Err 51

Meaning: On the power-on self test, the unit recognizes an operation of one of the front panel keys.

Cause: Attempt of selecting a current mode before end of power-on self test, jamming of a key or fault of a I^2C interface component at the front board.

Repair: If not caused by operation, there is a fault at the front board A1 (50).

Err 58 (from software state 05)

Meaning: the numbers of version of master EPROM and slave EPROM are not identical.

Cause: On software exchange, only one of both EPROMs has been exchanged (see item 4.3 for EPROM locations).

Repair: Change of other EPROM, too.

Err 59

Meaning: The actual values IM1 and IM2 of both of the current transducers at the monopolar RF generator board are not identical.

Cause: Failure of one of the current transducers or of the I^2C bus port for this signals at the monopolar board.

Repair: Change monopolar RF generator board A3/A8 (52).

Err 60

Meaning: The actual values IB1 and IB2 of both of the current transducers at the monopolar RF generator board are not identical.

Cause: Failure of one of the current transducers or of the I^2C bus port for this signals at the monopolar board.

Repair: Change bipolar RF generator board A4 (53).

PIn *(from state 0807, from serial end number 0974)*

Meaning: Due to wrong placing of a 4 Millimeters plug of an instrument connection cable at the monopolar output 1, RF output current flows a wrong path which results in poor clinical performance of the current and may result in damage of components. The unit protects itself against this by cutting off the RF current and displaying the message "PIn" in the display for monopolar coagulation power setting as long as the foot switch is operated. Because this is not a failure of the unit or accessories but an operation fault, this message is not displayed as "Err".

Cause: The plug of an instrument connection cable is plugged in one of the control sockets which are receptacles for the pins of three pin connectors as usual with single-use accessory, or is plugged into the ring gap of the coax connector.

Repair: Correct plugging of the instrument connection cable plug into the center conductor of the coax socket at the right side of the oval recess.

4. Service Adjustments

4.1 Checks and Alignment

This section is *an excerpt* of the test procedures which are valid for all versions of the ME 401 at the manufacturer's site.

Before alignments are performed, it is essential to identify the version of the unit (see section 5) and to apply the version of the test and alignment procedure valid for this unit.

From serial end number 0385, the matching of some current modes is varied. Additional, with the contact coagulation 2, the output power is varied with the basic mode of current generation. Because of this, there are two different test and alignment procedures which are differed by the designations procedure 1 and procedure 2 in the following:

- **Procedure 1**: Versions 0103, 0303, 0204, 0304 (up to serial end no. 0384)
- **Procedure 2:** Versions 0406, 0506, 0606, *0706, 0807 and 0810* (from serial end no. 0385)

Both of the test and alignment procedures are unified in this section. Differences *or amendments* are pointed out where they are valid.

4.1.1 Test Means

- Visual check: Mirror
- Safety test: Bender Safety Tester μP 601 or similar unit
- Functional test,
- Alignment and RF power measurement: MARTIN RF power meter EPM2 or FM2907 or similar unit
  Digital multimeter class 1.5
- Aux. Test Means: Coax plug 1/4" with resistor 270 Ohms
  Coax plug 1/4" shorted
  Monopolar MARTIN handpiece or
  Monopolar handpiece US three-pin
  Set of monopolar measure cords
  Bipolar test adapter 08-022-00-19 *with symmetric measuring cable BI-COAG 08-008-00-14*, substitutional *symmetrical* Martin bipolar connection cable, 5 Meters long
  Monopolar and bipolar foot switch
  Screw driver for alignment

Attention! For measurement of monopolar RF power, *a normal handpiece shall be used where the connection cable to the RF power meter is plugged in instead of the electrode. This cable shall not be rolled up because the coil which will be established in this way may change the impedance matching which results in faulty measurements. The neutral electrode output may be conneted to the power meter with a short connection cable.*

For measurements of bipolar output power and RF leakage current, only the specified test adapter with symmetrical test cable, substitutional a symmetrical MARTIN bipolar forceps connection cable (grey) with 5 Meters length shall be used! The former coaxial bipolar forceps connection cable (black) shall no longer be used for alignments. Explanation as follows: From now, MARTIN only supplies the symmetric cable like all competitors do because it offers some advantages in application. This cable has a lower consumption of reactive power. Because of that, a generator which is matched to the former cable supplies a higher output voltage which results in a higher output power in case of a matched load. Then the overdose protection circuit of the ME 401 will become active. Because of that, the bipolar RF generator has to be set anew according to item 4.1.6.3 if a change to the symmetric cable will be done. From version 0807 (from serial end no. 0974) this setting is just done at the manufacturer's site. It is highly recommended to change the setting of units of former version to the new cable if there is the opportunity during safety checks or repairs. The former caxial cables may also be used with this new setting, the maximum output power with bipolar coagulation will be for 10 Percent less than nominal. This does not affect the bipolar cutting modes but the nominal impedance matching will be shifted from 500Ω to 800Ω.

4.1.2 Visual Checks

Check hardware state and compare with datas at the test record sheet and the rear side.

- **Front Panel:**
    - Correct placing of board in front panel
    - Correct placing and stick-on of front layout
    - Front panel correct assembled and tightened
    - Switchover point of keys "crispy"
    - Correct placing and correct position of turn of sockets
    - Check NE socket for correct latching with test plug
    - Check RF output sockets for safe hold with test plugs
    - Rotary knobs: No jamming on turn, correct height, not easy to detach, turning range 1 to 10 symmetric, mark clear visible
- **Wiring:**
    - PE conductor connected to PE terminal and fed through current transformer
    - Check single cable sets for correct guidance and connection
    - All connectors plugged tight
    - Flat connectors plugged deep until stop
    - Soldering tags and components not bended (hazard of shorting)
    - Placing of correct fuses
    - Correct labeling of fuses
    - Mains voltage: Check settings at the standby board and the mains transformer in accordance with item 4.3
    - potentiometer terminals not bended
    - Check settings of the DIL switches at the controller board in accordance with 4.4.

- **Labeling:**

  - Label "Protection Earth" beneath the PE terminal at the front left top
  - Label "High Voltage" at the case bottom in front of the RF output board
  - Label "Equipotential" under the equipotential terminal
  - CE label at the rear

- **Type label:**

Up to serial end number 0384 (Procedure 1):

martin Medizin-Technik	**Gebr. Martin Ludwigstaler Straße 132 D 78532 Tuttlingen**
ME 401 HF-Chirurgie	
100/115/127/230/240V~ 50/60 Hz 880VA Type CF Class I	
Monop :320W/700/1200 Ohm int 10s/30s Bip : 80W/100/ 400 Ohm 0,5MHz	
Bauartzul.-Kennz.: 01/M-328/94 Serial No.: MME4010304950384	
Made in Germany	

From serial end number 0385 (Procedure 2):

martin Medizin-Technik	**Gebr. Martin Ludwigstaler Straße 132 D 78532 Tuttlingen**
ME 401 HF-Chirurgie	
100/115/127/230/240V~ 50/60 Hz 880VA Type CF Class I	
Monop : 320W/350/800 Ohm int 10s/30s Bip : 80W/100/500 Ohm 0,5MHz	
Bauartzul.-Kennz.: 01/M-328/94 Serial No.: ME4010406950385	
Made in Germany	

- **Designation of fuses:**

Designations in accordance with the manufacturer's voltage settings beneath the mains terminal block. On change of mains voltage setting, this label is to be replaced corresponding to the new mains voltage!

100V~ T8A	115V~ T8A	127V~ T8A	230V~ T4A	240V~ T4A
POWER	**POWER**	**POWER**	**POWER**	**POWER**

- **Assembling:**

  - PE terminal undermost and tightened with lock washer
  - All screws tightened
  - Stands and fixing bolts receptacles at the bottom side mounted correct
  - All screws locked with lock washers
  - Boards not distorted and placed correct in holders
  - Correct position of turn of the sockets
  - No slack parts or turnings in the unit (turn unit around with top downwards and shake)

4.1.3 High Voltage Test

At the manufacturer's site, this test is performed to verify that the safety relevant insuation barriers will have the insulation strengh required for safety operation. Usually there is no need for this test in service. If it will be performed, a consecutive test of all functions shall be performed.

For this test, a HV generator is required. The following insulation barriers have to be tested with voltages as follows:

- Case/PE vs. mains terminals L/N: 1.5 kV
- Case/PE vs. bipolar output: 1.5 kV
- Case/PE vs. monopolar output 1: 5 kV
- Case/PE vs. monopolar output 2: 5 kV
- Case/PE vs. neutral electrode: 5 kV

Be sure that the mains switch at the rear is set to on.

Because normally no HV test generator is taken with to outdoor service, the following substitute test may be performed *if required*:

- Switch on unit and set to spray coagulation at 100 Watts.
- Connect foot switch and connect the monopolar output 1 (right socket) to the equipotential terminal. Plug shorted coax test plug into NE socket.
- Activate monopolar coagulation for 30 Seconds.
- Connect neutral electrode terminal to equipotential terminal. Monopolar sockets remain free.
- Activate monopolar coagulation for 30 Seconds.
- Set unit to bipolar cutting 2 at 80 Watts and connect bipolar foot switch.
- Connect successively both of the bipolar cutting terminals to the equipotential terminal and activate bipolar cutting for 30 Seconds.

4.1.4 IEC 601 Safety Test

- Connect unit to safety tester.

- Settings at the unit: monopolar and bipolar cutting 2, contact coagulation 1. All rotary knobs at left end, mains power switched on.

- Setting up the safety tester and performing the safety test:

  - Switch on mains power for tester.
  - Eventually follow order "turn mains plug" (symmetric mains plug only)
  - Enter "+" key
  - Enter date (in case of error enter "C" key)
  - Test according to: IEC 601 (enter lower key next to display or "+")
  - Operation mode: Classification
  - Protection class: I
  - Mains cord: Detachable
  - Classification: CF
  - Patient circuit terminals: Enter "4" and "+"
  - Patient leakage current with voltage: no
  - Test, classification: Complete test
  - Test run: Automatic
  - Printout of limits: No
  - Confirmation with "+"
  - Start test run (enter "+")
  - In case of request " mains switch on?"-switch on and enter "+"
  - Unit will be switched on during test run, the lamps will light and a short sound signal will occur.
  - After test run enter serial number and confirm with "+". The test report will be printed.
  - Check test results for plausibility and keeping the limits.

Attention !

After any manipulation at the electric circuits of the unit,

this safety test

has to be performed anew !

4.1.5 Check of Functions of the Front Panel

- **Switch on unit and check sequence of power-on self test:**

- Version numbers of operation code, ROM tables and software state
- All segments of the numeric dislay
- Key illumination
- Lamps for RF indication and NE alarm
- Correct displayed bipolar instrument code
- Correct loudness and melodic intervals of acoustic signals

- **Functional test of keys:**

    - Mutual release of monopolar cutting selection keys
    - Mutual release of monopolar coagulation selection keys
    - Mutual release of bipolar cutting selection keys
    - Toggle mode function of the automatic bipolar coagulation key
    - Function of the standby key

- Note:

In case of "virginal" EEPROM at the controller board, no key will light after power-on self test, the unit cannot be activated. In this case, one key from each selection group must be selected.

- **Functional check of setpoint potentiometers:**

    - Set each potentiometer at the left and the right end and observe the display:

        - Monopolar cutting: Display from 8 to 320
        - Contact coagulation 1: Display from 8 to 250
        - Contact coagulation 2: Display from 8 to 250 (up to HW 03, up to end no. 0384)
        - Contact coagulation 2: Display from 5 to 150 (from HW 04, from end no. 0385)
        - Spray coagulation: Display from 5 to 100
        - Bipolar cutting: Display from 4 to 80
        - Bipolar coagulation: Display from 4 to 80

4.1.6 Alignment and Functional Checks

4.1.6.1 Alignment and Check of Functions of the RF Output Board on Change

- **Alignment of neutral electrode monitor:**

    - Plug 1/4" coax plug with 270 Ohms resistor into NE socket.

    - Connect voltmeter to test point "NE" at the RF output board vs. ground and adjust to 2.30V with trimmer "NE" (left side).

- **Alignment of automatic bipolar coagulation:**

    - Connect voltmeter to test point "BA" at the RF output board vs. ground and adjust to 3.00V with the trimmer "BA" on the right top.

- **Alignment of bipolar instrument identification:**

    - Connect bipolar test adapter or test box to bipolar output and switch to resistor "1" (68kOhms).

    - Connect voltmeter to test point "IC" at the RF output board vs. ground and adjust to 1.00V with the trimmer "IC" top at the right of the middle.

    - On operating the automatic bipolar key "01" has to be displayed.

    - Switch off resistor. The display must change to "00".

    - Switch on resistor "5" (33kOhms). The voltmeter at test point "IC" has to display 1.70V +/- 0.10V.

- **Alignment of monopolar RF leakage current limitation:**

    - Set unit to spray coagulation at 100 Watts.

    - Set RF power meter to 200 Ohms.

    - Connect monopolar output 1 (right socket) for leakage current measure (use shorted NE coax plug).

    - Activate monopolar coagulation and adjust leakage current to 95 mA with the trimmer "IF" down in the middle of the RF output board. The begin of limitation is audible by a jitter of the acoustic signal.

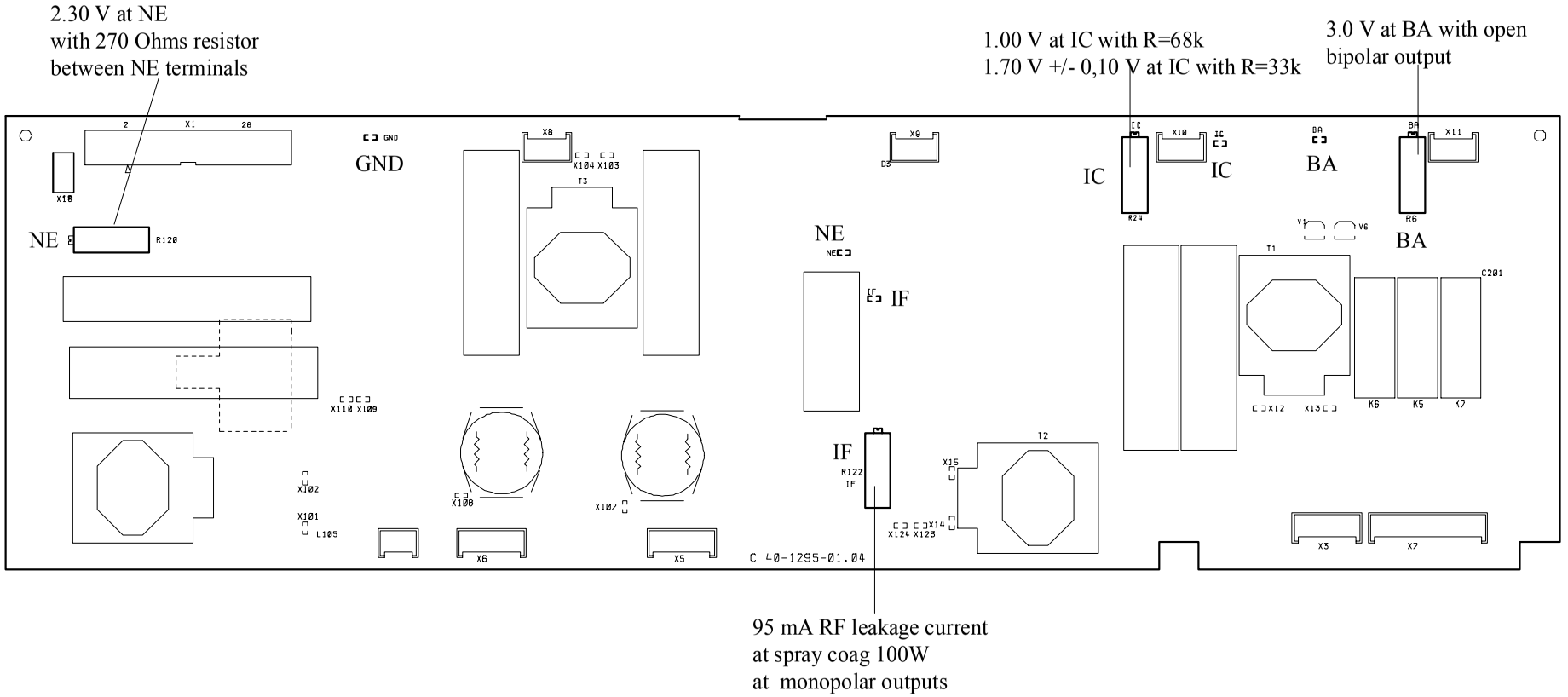
    - Connect RF power meter to output 2 (left socket) and activate output 2 for coagulation by means of a short banana plug cable. If the leakage current is less or equal to 95 mA, then keep this adjustment.

    - If the leakage current is greater than 95mA, then adjust to 95 mA with trimmer "IF" at the middle of the RF output board.

    - Connect RF power meter to NE terminal and activate monopolar coagulation. Compare displayed RF leakage current with that from the manufacturer's test report.

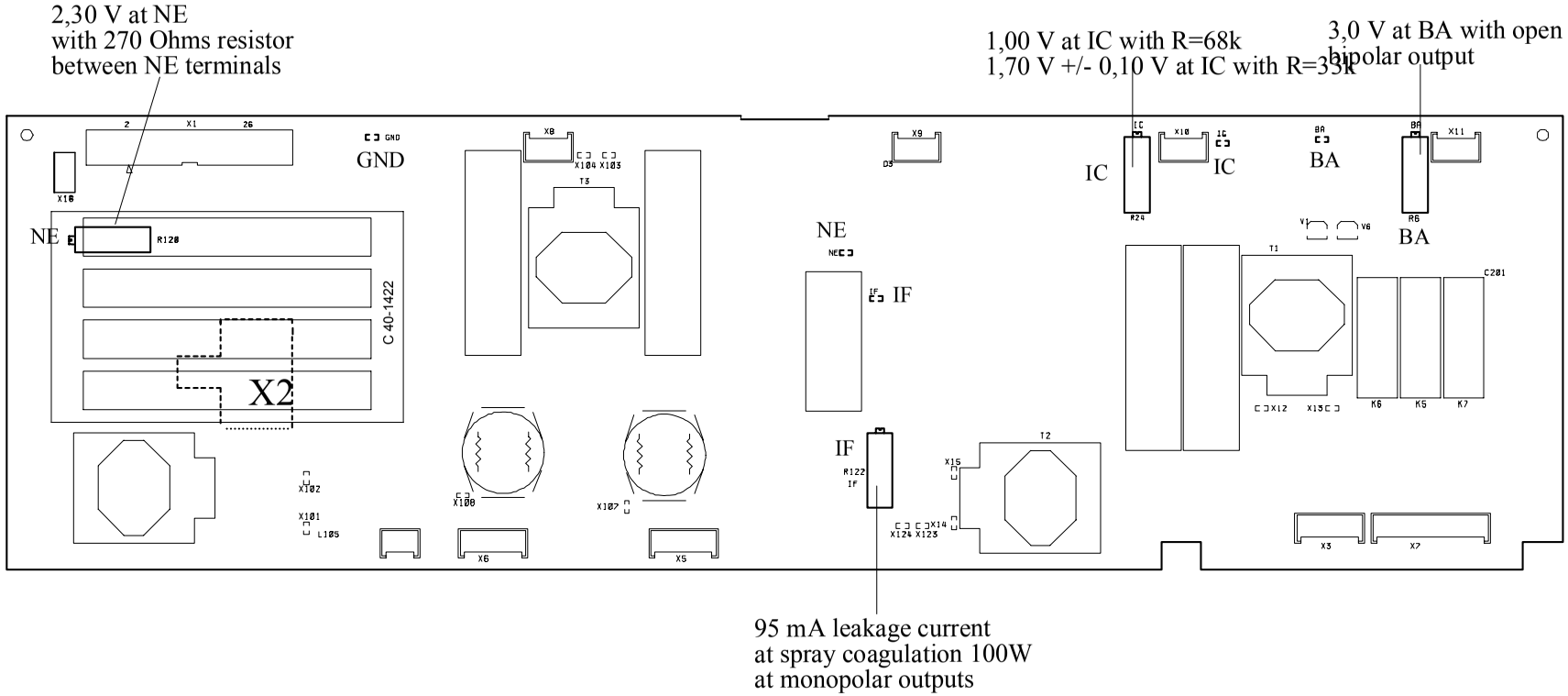
    - Repeat the last five steps with the unit set to "Urologic Cutting 2", maximum power. If one of the measurements shows a RF leakage current greater than 100mA, then set current below 100mA with trimmer "IF".

Attention! Use cords as short as possible for this test. Testing with long cords, e. g. with the active electrode handle, leads to faulty results.



Test and alignment points RF output PCB A2

File: DES2U.DRW



TEST AND ALIGNMENT POINTS RF OUTPUT PCB A7

File: DES2BE.DRW

- **Functional check for activation:**
  - Set all of the four potentiometers to the left.
  - Plug shorted coax plug or test cord to the NE socket and perform the following checks:
  - Perform functional check for activation of cutting and coagulation with MARTIN handpiece or test box at both monopolar terminals.
  - Perform functional check for activation of cutting and coagulation with US three-pin handpiece or test box at both monopolar terminals.
  - Perform functional check for activation of cutting and coagulation with monopolar foot switch or test box.
  - Perform functional check for activation of bipolar cutting and bipolar coagulation with bipolar adapter or test box.
  - Perform functional check for activation of bipolar cutting and bipolar coagulation with bipolar foot switch or test box.

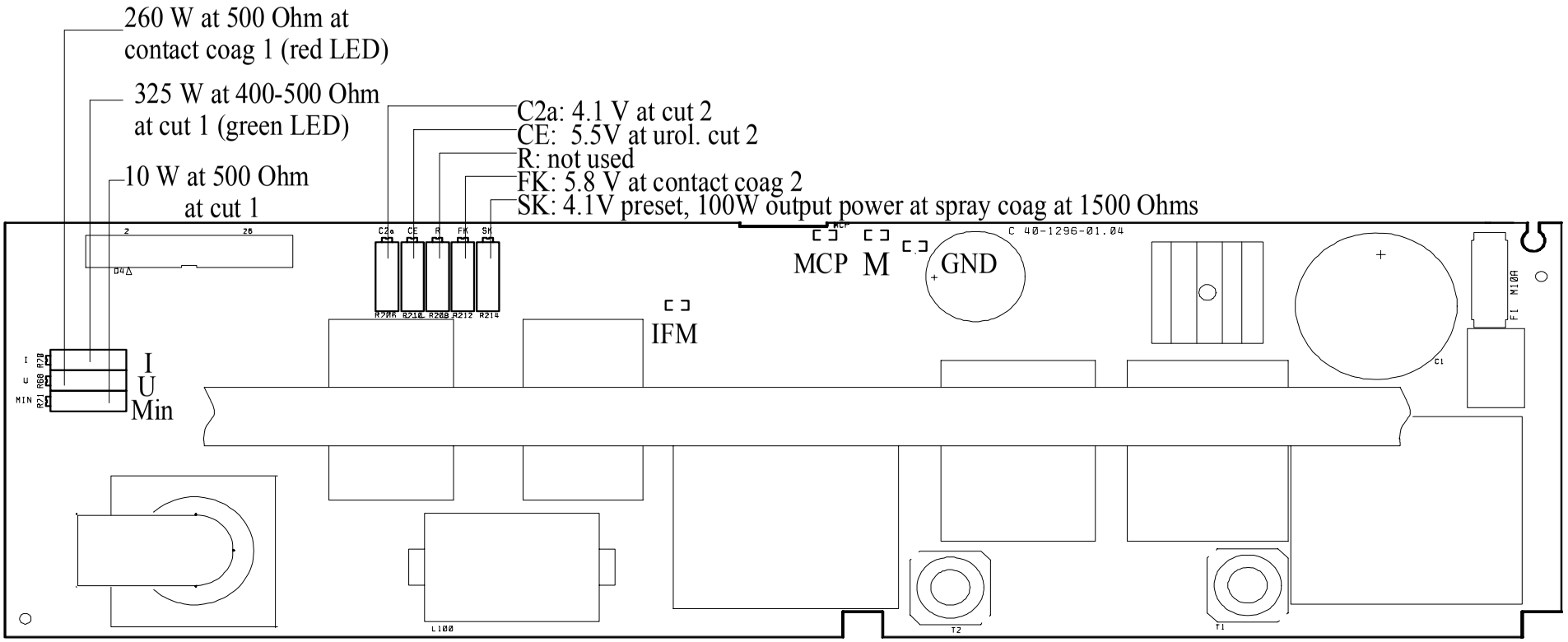
4.1.6.2 Alignment of Functions of the Monopolar RF Generator Board on Change

- **Adjustment of degrees of modulation:**
  - Set all of four potentiometers to left end.
  - Plug shorted coax plug or measure cord into NE socket.
  - Connect voltmeter to test point "M" at the monopolar generator board vs. ground and perform the adjustments as follows:
  - Select "Monopolar Cutting 2" and activate with foot switch or test box.
  - Adjust to 4.10V with trimmer "CII". Take care that the DIL switch at the controller board is set to off position.
  - Select "Urologic Cutting 2" and activate this function.
  - Adjust to 5.50V with trimmer "CE".
  - Select "Contact Coagulation 2" (medium coagulation key) and activate monopolar coagulation.
  - Adjust to 5.80V with trimmer "FK".
  - Select "Spray Coagulation" and activate monopolar coagulation. Pre-adjust to 4.1V with the trimmer "SK".

4.1.6.2.1 Monopolar RF Generator Board A3: Adjustment of Nominal Output Power

This item is valid for the adjustment of the output power of the monopolar RF generator board A3 which is assembled in the configurations 0103, 0303, 0204 and 0304 (up to serial end number 0384) and corresponds to procedure 1:

- Set RF power meter to a load resistance of 500 Ohms.
- Set unit to "Contact Coagulation 1".
- Power setting to 250.
- On activation of monopolar coagulation, adjust to an output power of 260 Watts with the trimmer "U" at the left side of the monopolar board (access through an orifice at the left side of the case). Note that the red LED at the monopolar board will light.
- If the green LED would light, turn trimmer "I" so far that the green LED turns to dark and the red LED will light.
- Set unit to "Monopolar Cutting 1" and power setting to 320. Set power meter to the resistance recorded in the test report sheet.
- On activation of monopolar cutting, adjust output power to 325 Watts (access through an orifice at the left side of the case). Note that the green LED at the monopolar board will light.
- This previous check/adjustment is to repeat alternately until both adjustments are correct:
- Setting for "Monopolar Cutting" to 10, short before left end.
- Set power meter to 500 Ohms.
- On activation of monopolar cutting, adjust output power to 10 Watts (141 mA) with the trimmer "Min" (access through an orifice at the left side of the case, 10 Watts correspond to 141 mA at 500 Ohms).
- Set power to 160 and activate monopolar cutting.
- Compare actual value displayed by the power meter with test report sheet and check for compliance with tolerances.
- Set power meter to 1500 Ohms.
- Set power of the unit to 320.
- Activate monopolar cutting, compare displayed value with test report sheet and check for compliance with tolerances.



Test and alignment points monopolar RF generator PCB A3

File: DES4U.DRW

- Select "Spray Coagulation" at the unit and set power to 100.

- Activate monopolar coagulation and adjust output power to 100 Watts at 1500 Ohms with trimmer "SK". Turn clockwise for more power, counterclockwise for less power. **Attention!** If the turning will be increased beyond a maximum power of approx. 105 Watts, the output power will decrease on further clockwise turn. This means that there are two points of alignment for 100 Watts. However, at this second point of alignment the power consumption of the generator is higher which may result in a cutoff of activation by the safety circuit, especially in case of small or medium power settings. In doubt check output power after adjustment at several power settings.

- If the RF leakage monitor will become active, turn trimmer "IF" until 100 W can be adjusted.

- Set unit to "Monopolar Cutting 2a" (select key for "Monopolar Cutting 2" and check the DIL switch 2 at the controller board for being set to off).

- Set power to 320.

- Set power meter to 500 Ohms.

- On activation of monopolar cutting compare the value displayed by the power meter with the test report sheet and check for compliance with the tolerances.

- Set unit to "Urologic Cutting 1".

- Set power to 320.

- Set power meter to 700 Ohms and activate monopolar cutting.

- Compare displayed value with test report sheet and check for compliance with tolerances.

- Set unit to "Urologic Cutting 2".

- Set power to 320.

- Set power meter to 800 Ohms and activate monopolar cutting.

- Compare displayed value with test report sheet and check for compliance with tolerances.

- Set unit to "Contact Coagulation 2".

- Set power to 250.

- Set power meter to 500 Ohms.

- Activate monopolar coagulation.

- Compare displayed value with test report sheet and check for compliance with tolerances

- Check monopolar RF leakage currents according to 4.1.6.1 and adjust if required.

PRÜFPROTOKOLL TEST REPORT **- ME 401 -**

(Muster eines Prüfprotokolls entsprechend Abgleich 1 für Geräte bis HW 3 (bis Serienendnummer 0384)

*QS*10*94**********

Serien-Nr.: Netzspannung : [**230 V**] [V]
Series-No. Mains voltage

1. Sichtkontrollen durchgeführt Name :_____
   Visual inspections performed Name
2. Hochspannungsprüfung / Funktionsprüfung Name :_____
   High voltage test / Functional test Name
3. Sicherheitsprüfung nach EN 60601
   Saftey inspection according to EN 60601
   Ausdruck des Prüfgerätes: Printout of the testing unit:

Space for IEC 601 safety tester printout

Meßergebnisse Position 3 i.O.: Name:
Measuring results position 3 o.k. Name

.....

4. Funktionsprüfungen: Functional tests

5. Ausgangsleistungen: Power outputs:
   KK1 (250/250± 50W/ 500Ω)=_____W
   KK2 (250/200-300W/ 500Ω)=_____W

   CUT1 (320/320± 64W/ ___Ω)=_____W SK(100/100± 20W/1500Ω)=_____W
   CUT1 (320/150-200W/1500Ω)=_____W
   CUT1 (160/128-192W/ 500Ω)=_____W

   CUT2a(320/256-384W/ 500Ω)=_____W BK(80/ 80± 16W/ 100Ω)=_____W
   CUTU1(320/256-384W/ 700Ω)=_____W BC1(80/ 80± 16W/ 600Ω)=_____W
   CUTU2(320/256-384W/ 800Ω)=_____W BC2(80/ 64- 96W/ 600Ω)=_____W

6. Netzstromaufnahme: (230V) [AV] Mains current consumption:
   standby 230V (< 0,2 A)=_____A
   CUT E (320/800Ω) (< 3,0 A)=_____A

7. HF-Ableitströme : (nach IEC 601-2 §19.102, SK: 100/200Ω)
   HF-leakage currents (according to IEC 601-2 §19.102, SK: 100/200Ω)

   Monopolar 1 (<100mA)=_____mA Bipolar 1 (<80mA) =_____mA
   Monopolar 2 (<100mA)=_____mA
   NE (<100mA)=_____mA

   Prüfergebnisse Pos.4-7 i.O. Datum: Name:
   Test results position 4-7 o.k. Date Name

.....

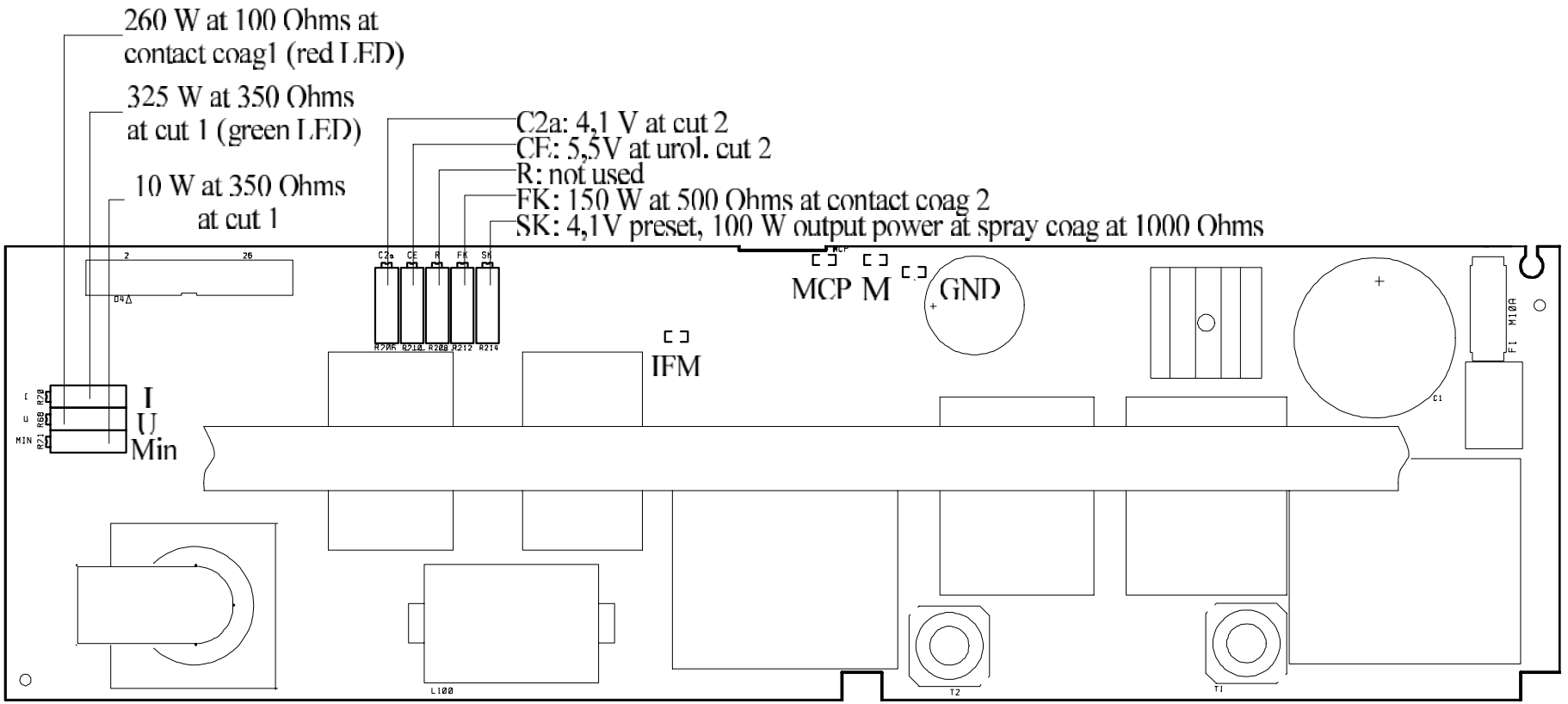
8. Dauertest (360 Schalt.;5/15Sek.;2Std.) Name:
   Burn in test (360 cycles;5/15 sec.;2hrs.) Name

Sample of a test report according to procedure 1 for units up to HW 3 (up to serial end number 0384)

4.1.6.2.2 Monopolar RF Generator Board A8: Adjustment of Nomonal Output Power

This item is valid for the adjustment of the output power of the monopolar RF generator board A8 which is assembled in the units with hardware state from 04 (from serial end number 0385) and corresponds to procedure 2:

- Set RF power meter to a load resistance of 100 Ohms.
- Set unit to "Contact Coagulation 1", Power setting to 250.
- On activation of monopolar coagulation, adjust to an output power of 250 Watts with the trimmer "U" at the left side of the monopolar board (access through an orifice at the left side of the case). Note that the red LED at the monopolar board will light.
- If the green LED would light, turn trimmer "I" so far that the green LED turns to dark and the red LED will light.
- Set unit to "Monopolar Cutting 1" and power setting to 320. Set power meter to a resistance of 350 Ohms.
- On activation of monopolar cutting, adjust output power to 320 Watts (access through an orifice at the left side of the case). Note that the green LED at the monopolar board will light.
- This previous check/adjustment is to repeat alternately until both adjustments are correct:
- Setting for "Monopolar Cutting" to 10, short before left end.
- On activation of monopolar cutting, adjust output power to 10 Watts (170 mA) with the trimmer "Min" (access through an orifice at the left side of the case, 10 Watts correspond to 170 mA at 350 Ohms).
- Set power to 160 and activate monopolar cutting.
- Compare actual value displayed by the power meter with test report sheet and check for compliance with tolerances.
- Set power meter to 1500 Ohms.
- Set power of the unit to 320.
- Activate monopolar cutting, compare displayed value with test report sheet and check for compliance with tolerances.
- Select "Spray Coagulation" at the unit and set power to 100.
- Activate monopolar coagulation and adjust output power to 100 Watts at 1000 Ohms with trimmer "SK". Turn clockwise for more power, counterclockwise for less power. **Attention!** If the turning will be increased beyond a maximum power of approx. 105 Watts, the output power will decrease on further clockwise turn. This means that there are two points of alignment for 100 Watts. However, at this second point of alignment the power consumption of the generator is higher which may result in a cutoff


260 W at 100 Ohms at
contact coag1 (red LED)
325 W at 350 Ohms
at cut 1 (green LED)
10 W at 350 Ohms
at cut 1
C2a: 4,1 V at cut 2
CE: 5,5V at urol. cut 2
R: not used
FK: 150 W at 500 Ohms at contact coag 2
SK: 4,1V preset, 100 W output power at spray coag at 1000 Ohms
MCP M
GND
IFM
I
U
Min

TEST AND ALIGNMENT POINTS MONOPOLAR RF GENERATOR PCB A8

File: DES4BE.DRW

of activation by the safety circuit, especially in case of small or medium power settings. In doubt check output power after adjustment at several power settings.

- If the RF leakage monitor will become active, turn trimmer "IF" until 100 W can be adjusted.
- Set unit to "Monopolar Cutting 2a" (select key for "Monopolar Cutting 2" and check the DIL switch 2 at the controller board for being set to off).
- Set power to 320.
- Set power meter to 350 Ohms.
- On activation of monopolar cutting, compare the value displayed by the power meter with the test report sheet and check for compliance with the tolerances.
- Set unit to "Urologic Cutting 1".
- Set power to 320.
- Set power meter to 350 Ohms and activate monopolar cutting.
- Compare displayed value with test report sheet and check for compliance with tolerances.
- Set unit to "Urologic Cutting 2".
- Set power to 320.
- Set power meter to 800 Ohms and activate monopolar cutting.
- Compare displayed value with test report sheet and check for compliance with tolerances.
- Set unit to "Contact Coagulation 2".
- Set power to 150.
- Set power meter to 500 Ohms
- Activate monopolar coagulation.
- Adjust output power to 150 Watts at 500 Ohms with trimmer "FK". Turn clockwise for more power, counterclockwise for less power. **Attention!** If the turning will be increased beyond a certain maximum power, the output power will decrease on further clockwise turn. This means that there are two points of alignment for 150 Watts. However, at this second point of alignment the power consumption of the generator is higher which may result in a cutoff of activation by the safety circuit, especially in case of small or medium power settings. In doubt check output power after adjustment of trimmer "FK" at several power settings.
- Check monopolar FR leakage currents according to 4.1.6.1 and adjust if required.

PRÜFPROTOKOLL TEST REPORT **- ME 401 -**

*QS*08*95**********

Serien-Nr.: Netzspannung : [**230 V**] [V]
Series-No. Mains voltage

1. Sichtkontrollen durchgeführt Name :_____
Visual inspections performed Name

2. Hochspannungsprüfung / Funktionsprüfung Name :_____
High voltage test / Functional test Name

3. Sicherheitsprüfung nach VDE 0750 bzw. IEC 601
Saftey inspection according to VDE 0750 and/or IEC 601
Ausdruck des Prüfgerätes: Printout of the testing unit:

Space for IEC 601 safety tester printout

Meßergebnisse Position 3 i.O.: Name:
Measuring results position 3 o.k. Name

4. Funktionsprüfungen: Functional tests

5. Ausgangsleistungen: Power outputs:
KK1 (250/250± 50W/ 100Ω)=_____W
KK2 (150/150± 30W/ 500Ω)=_____W

CUT1 (320/320± 64W/ 350Ω)=_____W SK(100/100± 20W/1000Ω)=_____W
CUT1 (320/150-200W/1500Ω)=_____W
CUT1 (160/128-192W/ 350Ω)=_____W

CUT2a(320/256-384W/ 350Ω)=_____W BK(80/ 80± 16W/ 100Ω)=_____W
CUTU1(320/256-384W/ 350Ω)=_____W BC1(80/ 80± 16W/ 500Ω)=_____W
CUTU2(320/256-384W/ 800Ω)=_____W BC2(80/ 64- 96W/ 500Ω)=_____W

6. Netzstromaufnahme: (230V) [AV] Mains current consumption:
standby 230V (< 0,2 A)=_____A
CUT E (320/800Ω) (< 3,0 A)=_____A

7. HF-Ableitströme : (nach IEC 601-2 §19.102, SK: 100/200Ω)
HF-leakage currents (according to IEC 601-2 §19.102, SK: 100/200Ω)

Monopolar 1 (<100mA)=_____mA Bipolar (<80mA) =_____mA
Monopolar 2 (<100mA)=_____mA (BC2: 80/200Ω)
NE (<100mA)=_____mA

Prüfergebnisse Pos.4-7 i.O. Datum: Name:
Test results position 4-7 o.k. Date Name

8. Dauertest (360 Schalt.;5/15Sek.;2Std.) Name:
Burn in test (360 cycles;5/15 sec.;2hrs.) Name

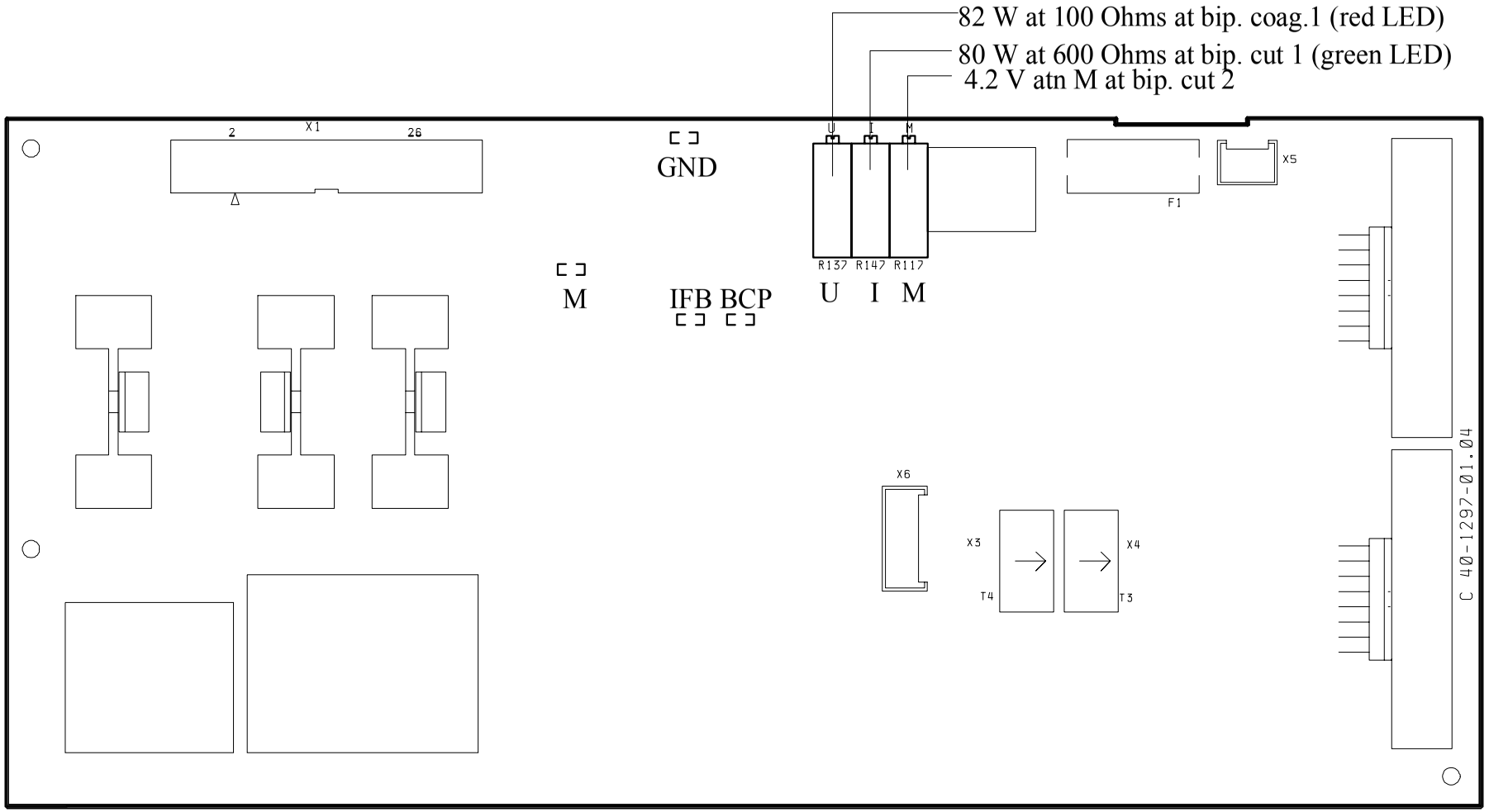
Sample of a test report according to procedure 2 for units from HW 04 (from serial end number 0385)

4.1.6.3 Alignment of Functions of the Bipolar RF Generator Board on Change

- **Adjustment of degree of modulation:**
  - Connect voltmeter to test point "M" at the bipolar RF generator board vs. ground.
  - Select "Bipolar Cutting 2" and activate bipolar cutting by foot switch, bipolar adapter or test box.
  - Adjust to 4.20V with trimmer "M".

- **Adjustment of and check for nominal RF output power:**
  - Set power meter to 100 Ohms.
  - Connect unit to the power meter using the bipolar test adapter *and the symmetric test cable (grey)* for measurement of "Bipolar Coagulation".
  - Set power for bipolar coagulation to 80.
  - Activate bipolar coagulation with foot switch *or* bipolar adapter.
  - Adjust output power to 82 Watts with trimmer "U". Note that the red LED will light.
  - If the green LED lights then turn trimmer "I" until the red LED will light instead of the green one.
  - *Set power meter to 800 Ohms. With units of hardware state up to 3 (serial end no. up to 0384) the nominal impedance matching in the test sheet is 600 Ohms, with units of hardware state 04 to 07 (serial end no. 0385 to 0973) it is 500 Ohms. This was not a change in impedance matching of the bipolar generator but results from an altered test procedure and the change to the symmetric connection cable.*
  - Connect unit to the power meter for bipolar cutting measure with the *symmetric* bipolar test cable and bipolar adapter. Select "Bipolar cutting 1" and set power setting of bipolar cutting to 80.
  - Activate bipolar cutting by foot switch *or* bipolar adapter.
  - Adjust to an output power of 80 Watts with trimmer "I". Note that the green LED will light.
  - Select the "Bipolar Cutting 2" key.
  - Activate bipolar cutting, compare displayed value with test report sheet and check for compliance with tolerances.

Note! Due to the change from the coaxial connection cable to the symmetrical, a change in impedance matching occured. With units of hardware state up to 07 which are still matched to the coaxial cable (black), the use of the symmetric cable (grey) may cause problems. So all of this units should be matched to the new cable! See item 4.1.1.



Alignment and test points bipolar RF generator PCB A4

File: DES6U.DRW

- **Bipolar RF leakage current check:**

  - Set power meter to 200 Ohms.

  - Connect unit for RF leakage current measure.

  - Check leakage current in the operation mode "Bipolar Cutting 2" with bipolar test adapter at both cable terminals. Compare the higher of both values with the record of the test report sheet.

Note: *With units of hardware state up to 07, the measured values of the RF leakage currents may differ from that registered in the test report sheet, because this values still were gained by use of the coaxial test cable. Also* tests with self-made cable adapters may result in values which are not in accordance with the values at the manufacturer's test report sheet.

For performing the measurement of output power and RF leakage currents associated with bipolar cutting as well as measurement of settings of the bipolar instrument identification, a bipolar test adapter is requred which is available from the MARTIN Service Center.

4.2 Voltage Selection in the Mains Circuit

The ME 401 can be matched to a number of global common mains voltages. Normally, the unit will be set at the manufacturer's site to the voltage present at the destination site. If there would occur the urge to change this setting, then proceed as follows:

- Detach mains cord and open unit according to item 2.2. Disconnect cable connection X3 at the standby board.

- Eventually remove carefully cover at the primary side of the mains transformer.

Setting to 230 Volts:

- Link soldering tags X6 and X7 at the standby board with a soldered jumper.

- Mains fuses: 4 Amps slow blow, two pcs. 5 X 20 Millimeters

- Eventually change cable line no. 6 of the primary connector to soldering terminal 6 of the transformer.

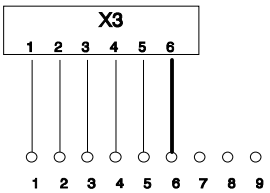
VOLTAGE SELECTION IN THE MAINS CIRCUIT

MAINS TRANSFORMER
(primary side)

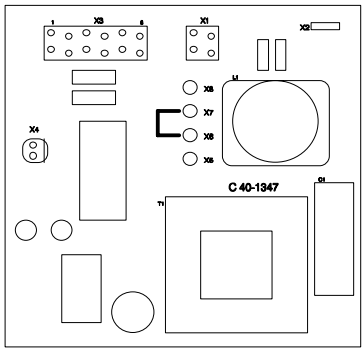
STANDBY PCB: JUMPER

File: SPGWU.DRW

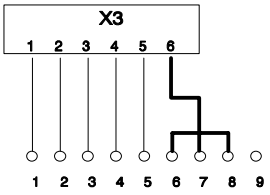
230V:



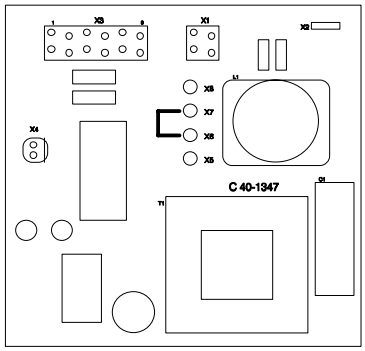
FUSES: 4A slow blow



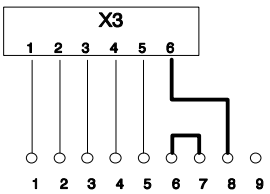
240V:



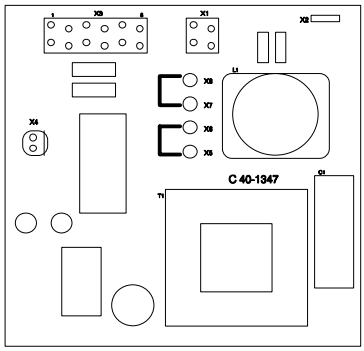
FUSES: 4A slow blow



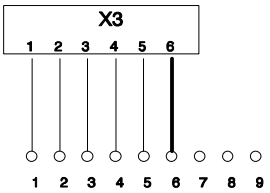
100V:



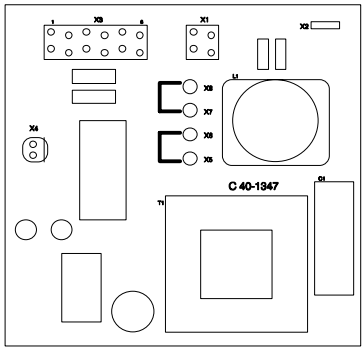
FUSES: 8A slow blow



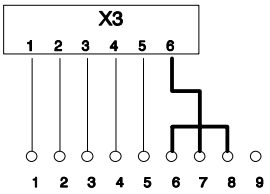
115V:



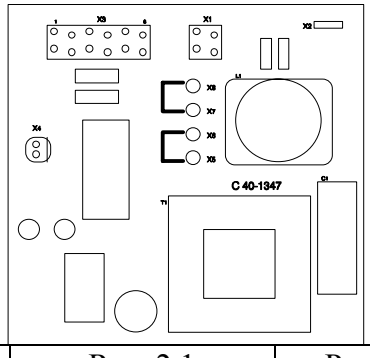
FUSES: 8A slow blow



127V:



FUSES: 8A slow blow



Setting to 240 Volts:

- Link soldering tags X6 and X7 at the standby board with a soldered jumper.
- Mains fuses: 4 Amps slow blow, two pcs. 5 X 20 Millimeters
- Change cable line no. 6 of the primary connector to soldering terminal 7 of the transformer. Connect terminal 6 and terminal 8 with a soldered wire under the cover.

Setting to 100 Volts:

- Link soldering tags X5 and X6 as well as X7 and X8 at the standby board with soldered jumpers.
- Mains fuses: 8 Amps slow blow, two pcs. 5 X 20 Millimeters
- Change cable line no. 6 of the primary connector to soldering terminal 8 at the transformer. Connect terminal 6 and terminal 7 with a soldered wire under the cover.

Setting to 115 Volts:

- Link soldering tags X5 and X6 as well as X7 and X8 at the standby board with soldered jumpers.
- Mains fuses: 8 Amps slow blow, two pcs. 5 X 20 Millimeters
- Eventually change cable line no. 6 of the primary connector to soldering terminal 6 of the transformer.

Setting to 127 Volts:

- Link soldering tags X5 and X6 as well as X7 and X8 at the standby board with soldered jumpers.
- Mains fuses: 8 Amps slow blow, two pcs. 5 X 20 Millimeters
- Change cable line no. 6 of the primary connector to soldering terminal 7 of the transformer. Connect terminal 6 and terminal 8 with a soldered wire under the cover.

After new setting perform the following steps:

- Rearrange cable connection X3 at the standby board and eventually place back primary terminal cover of mains transformer.
- Perform safety check according to 4.1.4.
- Close case according to 2.2.
- Replace label which indicates set mains voltage and mains fuses beneath the mains terminal block by an actual one.
- Record alterations to the unit's accompanying documents.

4.3 Settings of the Functional Options at the Controller Board

At the controller board, there is an eightfold miniature switch (DIL switch) which enables the change of a number of functions of the unit. The switches are of the meaning as follows:

S1 on: RF output power setting is changeable during RF activation.

S1 off: RF output power cannot be changed during RF activation.

S2 on: On selecting "Monopolar Cutting 2" the submode "Monopolar Cutting 2b" will be valid.

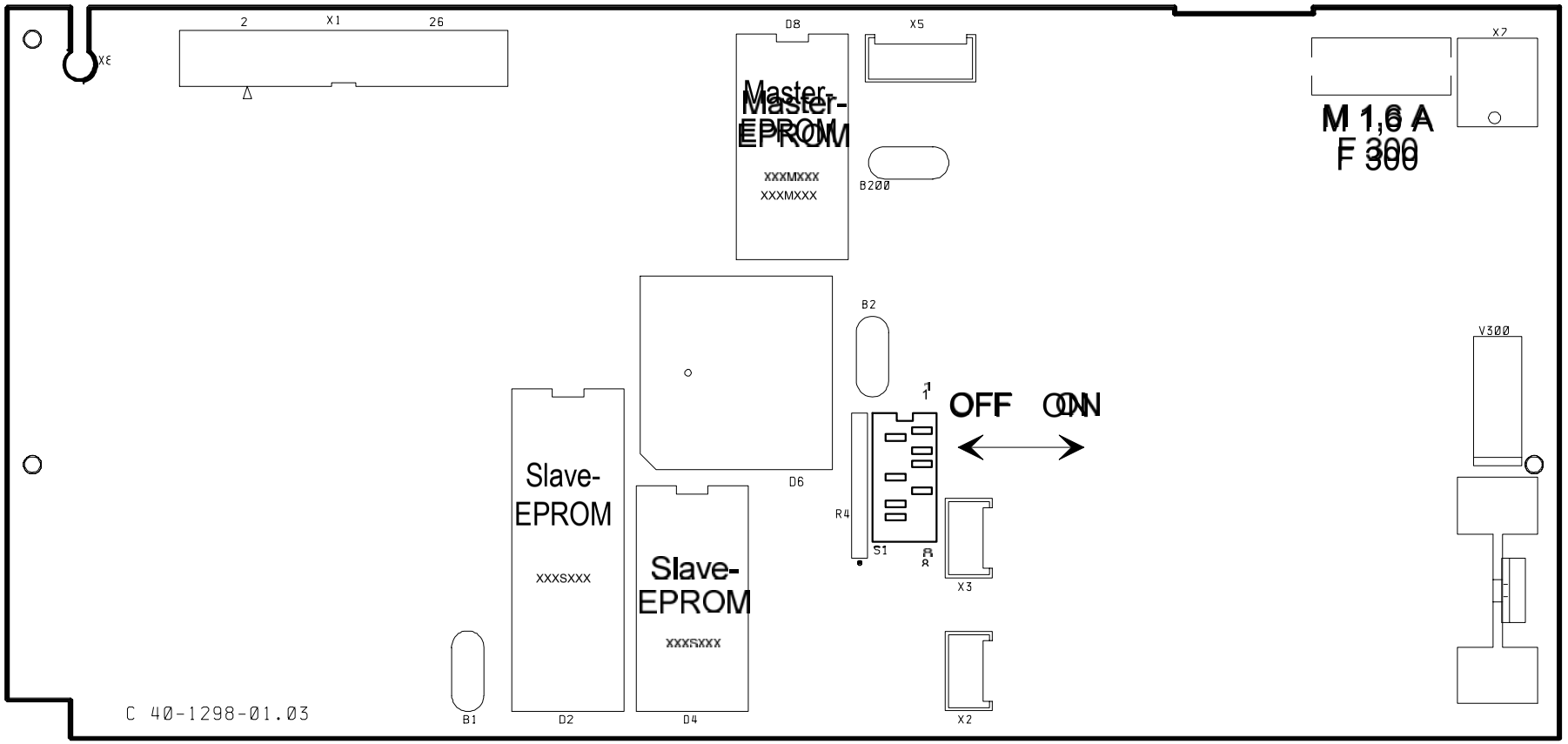
S2 off: On selecting "Monopolar Cutting 2" the submode "Monopolar Cutting 2a" will be valid.

S3 on: Activity of the monopolar RF leakage current limitation will be indicated as a jitter imposed to the acoustic activation signal.

S3 off: Activity of the monopolar RF leakage current limitation will not be indicated.

S4 on: The monopolar output 1 (right) is preferred to the monopolar output 2 (left).

S4 off: Both monopolar outputs are equal. That which will be activated first will have preference.



DIL switch settings at the controller PCB A5

DIL switch settings at the controller PCB A5

File: DFSBU.DRW

S5 on: Impedance alarm on. A single-sectioned neutral electrode monitored only by a cord loop will be considered to be faulty.

S5 off: Impedance alarm off. The unit will also accept single-sectioned neutral electrodes.

S6 on: After 15 Seconds of activation, the loudness of the acoustic activation signal will increase.

S6 off: The loudness of the activation signal remains unchanged.

S7 on: Not in use with units of hardware state up to 03 (with serial end numbers up to 0384). With the units of hardware state from 04 (with serial end number from 0385), the acoustic neutral electrode alarm occurs always in association with the optical alarm.

S7 off: The acoustic neutral electrode alarm occurs in association with the optical alarm on attempt of monopolar current activation.

S8 on: Not in use with units of hardware state up to 03 (with serial end numbers up to 0384). With the units of hardware state from 04 (with serial end number from 0385), the activation of the bipolar automatic function enables the bipolar coagulation current to be activated automatically on tissue contact of the instrument and to be automatically de-activated on reaching of a certain degree of coagulation.

S8 off: On activation of the bipolar automatic function, the coagulation current is only enabled to be de-activated automatically on reaching of a certain degree of coagulation. Activation is only possible via finger switch or foot switch.

Note: *With service manual rev. 2.0 the explanation of the functions of the switches S7 and S8 was interchanged! This fault should be corrected if rev. 2.0 is still in use.*

The unit leaves the manufacturer's site with the following settings:

- S1: On (right shift)
- S2: Off (left shift)
- S3: On (right shift)
- S4: On (right shift)
- S5: Off (left shift)
- S6: On (right shift)
- S7: Off (left shift)
- S8: Off (left shift)

4.4 Safety Checks to be Repeated Yearly

At this unit, the following checks are to be performed at least each twelfe months by persons who are in the position to perform such safety checks in an ordinary manner because of their training, their knowledge and their experience gained by practice and who are not subject to orders concerning this checking activities.

- Check visual unit and accessories for function impairing mecanical damages.
- Check safety relevant labels for readability.
- Check fuse cartridges for nominal current value and blow characteristic.
- On power-on self test, check visual the display digits for completeness of all segments as well as operation of key illumination and RF activation indication lamps for all of the four operation modes. Check sound generator signal for rising sequence.
- Perform functional check according to the user's instruction manual.
- Check for continuous change of output power corresponding to the sense of turn of the power setting potentiometers.
- Check for acoustc and optical alarms and cutoff of RF power activation on interruption of the neutral electrode.
- Compare setpoint and actual values of maximum output power fed to the nominal resistors according to item 1.2 at all outputs in the available operation modes.
- Check acoustic and optical signals at power activation.
- Measure resistance of PE circuit according to IEC 601-1. Maximum value: 0.2 Ohms. Do not measure versus equipotential terminal but versus bare parts of the case e. g. screws. Units of hardware state from 04 (from serial end number 0385) have two threaded borings at the rear side where contact could be made using a M4 screw.
- Measure leakage current of the unit according to IEC 601-1. Maximum value: 500 Microamps.
- Measure patient leakage current according to IEC 601-1. Maximum value: 10 Microamps.

The leakage currents may override the first measured values for 50 Percent and additionally shall not override the maximum values mentioned above.

The first measured values can be seen from the attached test reports at the first setup of the unit. The safety check is to enter in the unit's booklet and test results are to be recorded.

If the unit is out of function and/or unsafe it is to be repaired or the user must be informed about the hazard associated with it.

Medizin-Technik

Test Report	ID No.: .....
Tester:	Serial No.: ME 401.....
Owner:	Manufacturer: **Martin Medizin-Technik** Kind of Unit: **Electrosurgery Unit** Type: **ME 401** Year of Production: .....

Test Standard: **EN 60601** ❑

Test Result:

❑ 1. Measurements see Reverse of this Test Report.

❑ 2. Points of no Compliance:.....
.....
.....
.....
.....
.....
.....
.....

❑ 3. No Faults or Faults which do not concern Safety. The unit may be operated for further Use.

❑ 4. The Unit may be operated for further Use if the Faults mentioned above are removed.

❑ 5. Errors which require Maintenence or repair of the Unit before next Operation else Patients, Users or Third Persons may be Object of Hazard.

Date: Signature: Next Date of Check:

Test Report Sheet for Repetitive Safety Checks, Front Face

Medizin-Technik

Tester: Current No.:

Test Report: **Type: ME 401** **Serial No.:**

	Correct	Uncorr.	N/A	Comm.
1. Type label				
2. User's Instruction Manual				
3. Labeling				
4. Operation Elements				
5. Equipotential Connector				
6. Genuine Accessories? (Else Designation of Manufacturer)				
7. Visual Check of RF Connection Cords				
8. Foot Switch at OP Waterproof and AP Proof				
9. No Output Power on Missing Neutral Electrode				
10. Monitoring Circuit of Neutral Electrode (Acoustic Signal				
11. Check for Operation of Hand and Foot Switch Control				
12. Check for Optical and Acoustig Signal on RF Activation				

13 RF Power Measurement (Maximum at Nominal Resistance)

Cutting 1 at 500 Ohms: ..... Watts
Cutting 2a at 500 Ohms: ..... Watts
Urologic Cutting 1 at 700 Ohms: .....Watts
Urologic Cutting 2 at 800 Ohms: .....Watts
Contact Coagulation 1 at 500 Ohms: .....Watts
Contact Coagulation 2 at 500 Ohms: .....Watts
Spray Coagulation at 1500 Ohms: ..... Watts
Bipolar Cutting 1 at 600 Ohms: .....Watts
Bipolar Cutting 2 at 600 Ohms: .....Watts
Bipolar Coagulation at 100 Ohms: ..... Watts

Comments:.....
.....
.....
.....

Electrical Measurements According to IEC 601

14. Insulation Resistance Mains versus Case: ..... MΩ
15. Insulation Resistance Applied Part: ..... MΩ
16. Measurement of Protective Earth Conductor Resistance ..... Ω
17. Low Frrequency Leakage Current, Normal Condition ..... µA
18. Low Frequency Leakage Current, Single Fault Condition ..... µA
19. Enclosure Leakage Current, Normal Condition ..... µA
20. Enclosure Leakage Current, Single Fault Condition PE Conductor ..... µA
21. Enclosure Leakage Current, Single Fault Condition Mains ..... µA
22. Patient Leakage Current, Normal Condition ..... µA
23. Patient Leakage Current, Single Fault Condition PE Conductor ..... µA
24. Patient Leakage Current, Single Fault Condition Mains ..... µA
25. Patient Auxiliary Current, Normal Condition: ..... µA
26. Patient Auxiliary Current, Single Fault Condition PE Conductor ..... µA
27. Patient Auxiliary Current, Single Fault Condition Mains: ..... µA
28. Patient Leakage Current with Voltage in Parallel to Applied Part: ..... µA
29. dto., Interchanged Phases: ..... µA

Unit Checked at: ..... **From:** .....

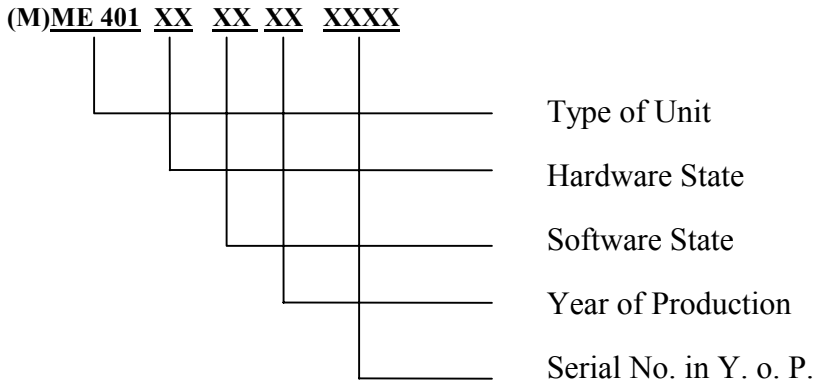
Test Report Sheet for Repetitive Safety Checks, Reverse

5. Alterations

5.1 Procedure

As experience shows, during their sales lifetime technical products undergo repeated technical alterations due to steady product improvements. To the service, this imposes the problem of having several versions of the same type of unit and prior to each repair it must be clarified which version is present.

Prior to any manipulation of the unit it is necessary to know the state of the version! At the ME 401 this is now indicated in the serial number:



5.2 Hardware State

The hardware state is defined by:

- Revision state of boards
- Revision state of mechanical construction
- Revision state of alignment

The boards are equipped with two labels. One of the labels contains the manufacturer's identity number C 40-XXXX and a continuing testing number with sign or identity number of the tester. The second label indicates the state of revision. If such a revision is present in the market, it will be concern of the following items.

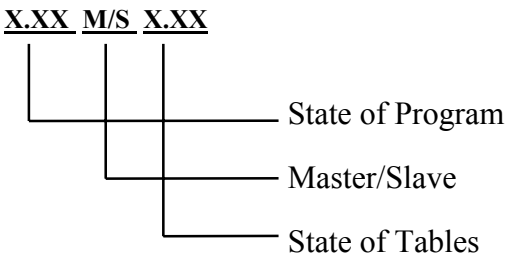
If such a board will be repaired at the manufacturer's site, it will get a third "repair" label. If possible, such boards will be updated to the actual state of revision and, after complete test procedure, will be used for repairs as exchange boards.

If it has the same MARTIN ordering number as the old part according to 2.1 (not to be confused with the manufacturer's identity code), a board with a higher state of revision may replace a board of lower state of revision (stepdown compatibility). **Vice versa, this is generally not valid!**

What makes the difference of new revisions with respect to their predecessors and which compatibilities are valid will be explained in the items corresponding to the different configurations. On release of a new revision, a description of the new configuration will be created and distributed by the Martin Service Center by the same way as this service documentation.

5.3 Software State

The operation codes and the tables for both microcontrollers are stored in two EPROMs which are labeled as follows:



The program state designates the version of the operation code. The last two of three digits form a continuing number which designate a stepdown-compatible revision while the first digit is associated to the hardware configuration. On an EPROM exchange, absolute care must be taken that this first digit is identical to that of the replaced one. If this digit would be incremented, then both of the following ones will be reset to zero.

The EPROM belonging to the master controller (see 2.7 and 4.3) has a letter "M" between the groups of numbers, that one belonging to the slave controller has a letter "S" between the numbers which are identical at both EPROMs. In case of mistaking both EPROMs the unit won't operate at all.

The state of table designates the version of memory stored parameters as tables of power characteristics, monitor threshold values and instrument identification. Especially the memory controlled instrument identification requires an appropriate software updating if a user wants to have a new bipolar instrument with identification. Such a new version results in an incrementation of the counter formed by the last two digits of the three-digit table version number. The first digit will be incremented if there is either a basic change in the structure of tables or an interrupt in continuity of function. This means that all table versions with the same first digit are compatible while only the most recent one features all functions established hitherto. On incrementing the first digit, both of the others are reset to zero.

On exchange of EPROMs for table updating care must be taken that the first digit of the program version will be kept and that the number formed by the following two digits will not be less than that at the former EPROM. On demand, pairs of EPROMs with special opcode/table combination have to be set up by the manufacturer. from this reason, tell actual hardware and software states of the unit when ordering.

An EPROM exchange always requires the change of **both EPROMs!**

5.4 Configurations

5.4.1 Configuration 0103

Serial numbers: ME 401 0103 94 0010 to ME 401 0103 94 0059

Software: 1.06M/S3.03

Front PCB A1: Version 00: Two coag keys, not compatible to other versions.

RF output PCB A2: Version 01. Use version *03* as spare part.

Monopolar PCB A3: Version 01. Use Version 02 as spare part.

Bipolar PCB A4: Version 01. Use Version *04 or 05* as spare part.

Controller PCB A5: Version 01 or 02, both are possible.

Standby PCB A6: Version 00

Additional notes:

- An update to configuration 0304 is uneconomic.
- The mains transformer is a version with lower secondary voltage AC2. **This transformers, recognizable at the charge codes E15 and E25 with identical labeling else shall not be disassembled from old units and be used as a spare part!** In case of low mains voltage, problems with the bipolar functions (error 26) may occur associated with this transformer. As a spare part exclusively the new transformer is avaiable.
- The front panel has only two orifices for monopolar coagulation keys. As a spare part, the new front panel with three orifices may be used, but the front layout is a spare part with its own ordering number according to 2.1.
- Particular, the top board holder (8) is fixed only with one fastening pin.

5.4.2 Configuration 0303

This version is no state of manufacture but an update of units of version 0103 using the alteration kit U 51-1010. The alterations contain:

- Addition of a protection diode at the RF output PCB to give protection against mishandling.
- Closing of the 4 Millimeter control sockets of the monopolar outputs with plastic plugs to give protection against mishandling.
- Exchange of the neutral electrode socket with insulation cup for quality reasons.

Serial numbers: ME 401 0103 94 0010 to ME 401 0103 94 0059

Software: 1.06M/S3.03

Front PCB A1: Version 00: Two coag keys, not compatible to other versions.

RF output PCB A2: Version 01, additional protection circuitry for component D1 with zener diode from alteration kit U 51-1010. Because the version number 02 is just used for the layout review of version 01, the version number 01 is kept unchanged. Use version 03 as spare part.

Monopolar PCB A3: Version 01. Use Version 02 as spare part.

Bipolar PCB A4: Version 01. Use version *04 or 05* as spare part.

Controller PCB A5: Version 00, 01. Both are possible as spare part.

Standby PCB A6: Version 00

Additional notes:

- An update to configuration 0304 is uneconomic.
- The mains transformer is a version with lower secondary voltage AC2. **This transformers, recognizable at the charge codes E15 and E25 with identical labeling else shall not be disassembled from old units and be used as a spare part!** In case of low mains voltage, problems with the bipolar functions (error 26) may occur associated with this transformer. As a spare part exclusively the new transformer is avaiable.
- The front panel has only two orifices for monopolar coagulation keys. As a spare part, the new front panel with three orifices may be used, but the front layout is a spare part with its own ordering number according to 2.1.
- Particular, the top board holder (8) is fixed only with one fastening pin.

5.4.3 Configuration 0204

This configuration is a design refinement of configuration 0103, essentially mechanical improvements are performed. The switching between both of the contact coagulation modes by changing the cutting mode is replaced by installation of a third coagulation select key between "soft" contact coagulation and spray coagulation. This reqired a new front PCB which is not compatible with the front PCB of configuration 0103. For increasing the operation stability in the case of mains undervoltage, the mains transformer was modified.

Serial numbers:	From ME 401 0204 94 0060 to ME 401 0204 95 0384
Software:	2.01M/S3.04 2.01M/S3.05 supports the instrument code
Front PCB A1:	Version 01: Three coag keys, not compatible with version 00. *As spare part, also version 02 can be used.*
RF output PCB A2:	Version 02. *Use version 03 as spare part.*
Monopolar PCB A3:	Version 02
Bipolar PCB A4:	Version 02, 03. Both versions *as well as versions 04 and 05* are possible as spare part.
Controller PCB:	Version 01
Standby PCB:	Version 00

If desired, the units of configuration 0204 can be updated to configuration 0304 using the alteration kit U 51-1010 (MARTIN ordering code 08-040-00-12). This is recommended in such cases when a unit is placed in a ward where the use of RF surgical instruments which are connected to the generator with a cable with 4 Millimeter plug is common.

5.4.4 Configuration 0304

Particular, this configuration is an update of units of the configuration 0204 using the alteration kit U 51-1010. The reason was the necessity to protect the units against destroying of the finger switch circuit by faulty plugging of an instrument connection cable into the 4 Millimeter control sockets. With respect to the configuration 0204, the following alterations are performed:

- Addition of a protection diode at the RF output PCB to give protection against mishandling.
- Closing of the 4 Millimeter control sockets of the monopolar outputs with plastic plugs to give protection against mishandling.
- Exchange of the neutral electrode socket with insulation cup for quality reasons.

Serial numbers:	ME 401 0304 94 0060 to ME 401 0304 95 0384 (partially 0204 update) ME 401 0304 96 0798 to ME 401 0304 96 0850 (100 Volt units) ME 401 0304 96 0883 to ME 401 0304 96 0894 (100 Volt units)
Software:	2.01M/S3.04
Front PCB A1:	Version 01: Three coag keys, not compatible with version 00. *Version 02 is also possible as spare part.*
RF output PCB A2:	Version 03. This version is gained by extension of version 02 using the alteration kit U 51-1010 (protection diode at D1).
Monopolar PCB A3	Version 02
Bipolar PCB A4:	Version 02, 03. Both versions *as well as versions 04 and 05* are possible as spare part.
Controller PCB:	Version 01
Standby PCB:	Version 00

If desired, the units of configuration 0204 can be updated to configuration 0304 using the alteration kit U 51-1010 (MARTIN ordering code 08-040-00-12). This is recommended in such cases when a unit is placed in a ward where the use of RF surgical instruments which are connected to the generator with a cable with 4 Millimeter plug is common.

5.4.5 Configuration 0406

This configuration is a design review of the configuration 0204. The reason was to improve the clinical properties of the "contact coagulation 2" which demands an extension of the monopolar RF output circuit. In detail this are the following alterations and extensions:

- New RF output PCB A7 which is not compatible with the output PCB A2 of former configurations.
- New monopolar RF generator PCB A8 which is not compatible with the RF generator PCB A3 of former configurations.
- Mechanical design review of the base casing which is not compatible to those of former configurations. The most noticable alterations are an equipotential connector pin recessed in a socket instead of the outstanding pin, riveted instead of adhesive case stands, addition of clamp springs to the insulated fixing bolt receptacles in the case bottom and an improvement in board fixing.

Serial numbers:	From ME 401 0406 95 0385 to ME 401 0406 95 0487
Software:	3.00M/S4.03. *For updating or replace use EPROM set 3.01M/S4.05.*
Front PCB A1:	Version 01: Three coag keys, not compatible with version 00. *Version 02 can also be used.*
RF output PCB A7:	Version 01. Not to be confused with RF output PCB A2! *Use versions 03 or 04 as spare part. To take advantage of the instrument cable connection fault protection circuit inherent with this versions, it is necessary to install the EPROM set 3.01M/S4.05 additionally.*
Monopolar PCB A8	Version 01. Not to be confused with monopolar PCB A3! *Use version 05 as spare part.*
Bipolar PCB A4:	Version 03. Also versions *04 or 05* may be used as spare part.
Controller PCB:	Version 01
Standby PCB:	Version 00

5.4.6 Configuration 0506

This configuration is derived from the configuration 0406. The reason was a quality problem with the neutral electrode sockets as used for the units of configuration 0406. The new hardware state shows the assembling of a new neutral electrode socket of better quality. This socket was also exchanged in units which are manufactured in configuration 0406, the hardware state became altered.

Serial numbers:	From ME 401 0506 95 0488 to ME 401 0506 96 0632 new units. From ME 401 0406 95 0385 to ME 401 0406 95 0487 partially altered.
Software:	3.00M/S4.03. *For updating or replace use EPROM set 3.01M/S4.05.*
Front PCB A1:	Version 01: Three coag keys, not compatible with version 00. *Version 02 can also be used.*
RF output PCB A7:	Version 00. Not to be confused with RF output PCB A2! *Use versions 03 or 04 as spare part. To take advantage of the instrument cable connection fault protection circuit inherent with this versions, it is necessary to install the EPROM set 3.01M/S4.05 additionally.*
Monopolar PCB A8	Version 01. Not to be confused with monopolar PCB A3! *Use version 05 as spare part.*
Bipolar PCB A4:	Version 03. Also versions *04 or 05* may be used as spare part.
Controller PCB:	Version 01
Standby PCB:	Version 00

For updating the configuration 0406 to 0506, the neutral electrode socket in the unit of configuration 0406 has to be replaced by the new neutral electrode socket with the Martin ordering code 08-024-00-34.

5.4.7 Configuration 0606

This configuration is derived from the configuration 0506. The reason was the introduction of the new layout of the front with "micro polka dot" pattern.

Serial numbers:	ME 401 0606 96 0633 *to ME 401 0606 96 0797*
Software:	3.00M/S4.03. *For updating or replace use EPROM set 3.01M/S4.05.*
Front PCB A1:	Version 01: Three coag keys, not compatible with version 00. *Version 02 can also be used.*
RF output PCB A7:	Version 00. Not to be confused with RF output PCB A2! *Use versions 03 or 04 as spare part. To take advantage of the instrument cable connection fault protection circuit inherent with this versions, it is necessary to install the EPROM set 3.01M/S4.05 additionally.*
Monopolar PCB A8	Version 01. Not to be confused with monopolar PCB A3! *Use version 05 as spare part.*
Bipolar PCB A4:	Version 03. Also versions *04 or 05* may be used as spare part.
Controller PCB A5:	Version 01
Standby PCB A6:	Version 00

With the mechanical dimensions, the new front layout is identical to that of all former configurations having three monopolar coagulation keys (from hardware state 02, from serial end number 0060) and so can be used as spare part for this configurations if the former layout is no more available.

5.4.8 Configuration 0706

This configuration differs from configuration 0606 especially in an improved version of the monopolar RF generator PCB with enhanced control range of the DC voltage controller and a change in wiring of the bipolar generator PCB which avoids the random occurence of "Err 26" messages with the consequence of improved management of mains undervoltage conditions. This is advantegeous for units which are fed from 100 Volts or 115 Volts mains supply.

Serial numbers:	*ME 401 0706 96 0851 to ME 401 0706 96 0882* *ME 401 0706 96 0895 to ME 401 0706 96 0973*
Software:	*3.00M/S4.03. For updating or replace use EPROM set 3.01M/S4.05.*
Front PCB A1:	*Version 01 or 02: Three coag keys, not compatible with version 00.*
RF output PCB A7:	*Version 01. Not to be confused with RF output PCB A2! Use versions 03 or 04 as spare part. To take advantage of the instrument cable connection fault protection circuit inherent with this versions, it is necessary to install the EPROM set 3.01M/S4.05 additionally.*
Monopolar PCB A8	*Version 04 or 05. Not to be confused with monopolar PCB A3!*
Bipolar PCB A4:	*Version 04. Also version 05 may be used as spare part.*
Controller PCB A5:	*Version 01*
Standby PCB A6:	*Version 00*

5.4.9 Configuration 0807

With respect to configuration 0706, this configuration contains an additional circuit at the RF output PCB for recognition of a faulty connection of an instrument connection cable at the monopolar output socket. For support of this function by the controller, a new software is installed.

Serial numbers:	*ME 401 0807 96 0974 to ME 401 0807 97 1139*
Software:	*3.01M/S4.04. Use version 3.01M/S4.05 for update to configuration 0810 or as spare part.*
Front PCB A1:	*Version 02: Three coag keys, not compatible with version 00. Version 01 can also be used.*
RF output PCB A7:	*Version 03. As a spare part, also version 04 can be used. Not to be confused with RF output PCB A2!*
Monopolar PCB A8	*Version 05. Not to be confused with monopolar PCB A3!*
Bipolar PCB A4:	*Version 04. Also version 05 may be used as spare part.*
Controller PCB:	*Version 01*
Standby PCB:	*Version 00*

For update of the connection fault protection to former configurations from 0406 (from serial end no. 0385), the RF output PCB has to be changed to version 03 or 04 and the EPROMs 3.01M/S4.05 have to be installed.

5.4.10 Configuration 0810

This configuration is the same as 0807 with the correction of a software fault and the bipolar setpoint tables of the EPROMs matched to the new symmetric bipolar connection cable.

Serial numbers:	*From ME 401 0810 97 1140*
Software:	*3.01M/S4.05*
Front PCB A1:	*Version 02: Three coag keys, not compatible with version 00. Version 01 can also be used.*
RF output PCB A7:	*Version 03 or 04. Not to be confused with RF output PCB A2!*
Monopolar PCB A8	*Version 05. Not to be confused with monopolar PCB A3!*
Bipolar PCB A4:	*Version 05*
Controller PCB:	*Version 01*
Standby PCB:	*Version 00*

Annex to Revision 2.1 for Version 0908

This annex describes the peculiarities of the units with hardware/software state 0908 which are manufactured in a limited edition. With respect to the former versions this unit have gained the improvements and additions as follows:

- Improved hemostasis of "Contact Coagulation 1".
- Reduction of components of lower frequencies in the output current of "Contact Coagulation 2" and "Spray Coagulation" which may be cause for faradisation effects.
- Compensation of leakage currents from the neutral electrode side.

To perform this, modifications of the monopolar section of the unit were required which result in the use of new PCBs. So the unit is not downwards compatible to the former versions, an update of former versions to 0908 is uneconomic. This modifications are as follows:

- New RF output PCB A9 (C40-1512) with modified impedance matching of the monopolar output which is not compatible to RF output PCBs A2 (C40-1295) and A7 (C40-1427).
- New monopolar RF generator PCB A10 (C40-1513) with modified RF output transformer which is not compatible to the RF generator PCBs A3 (C40-1296) and A8 (C40-1428).
- New controller software 3.01 M/S 5.00.

Due to this modification the procedure of alignment of the monopolar output power is changed. In case of new alignment of a unit, note specific deviations in item 4.1.6.

This annex consists of items which are to be considered as a complement to the items with same designation of the main part. If required, this annex can be splitted and linked to the corresponding items in the main part.

1.2.3 Configuration 0908 (serial end numbers 1051 to 1063)

Mains voltage:	100V/115V/127V/130V/240V 50-60Hz, to be set by change of soldered jumpers	
Input Power:	Approx. 1VA in the switch-off state, 42VA without RF activation, 880VA at maximum output power of both generators	
Output power:	Monop. Cutting 1:	max. 320W at 350 Ohms
	Monop. Cutting 2a:	max. 320W at 350 Ohms
	Monop. Cutting 2b:	max. 320W at 800 Ohms
	Urolog. Cutting 1:	max. 320W at 350 Ohms
	Urolog. Cutting 2:	max. 320W at 800 Ohms
	Contact Coag. 1:	max. 250W ***at 200 Ohms***
	Contact Coag. 2:	max. 150W at 500 Ohms
	Spray Coagulation:	max. 100W at 1000 Ohms
	Bipolar Cutting 1:	max. 80W at 500 Ohms
	Bipolar Cutting 2:	max. 80W at 500 Ohms
	Bip. Coagulation:	max. 80W at 100 Ohms
Crest factors:	Monop. Cutting 1:	1.8 at 320W at 350 Ohms
	Monop. Cutting 2a:	2.3 at 320W at 350 Ohms
	Monop. Cutting 2b:	2.5 at 320W at 800 Ohms
	Urolog. Cutting 1:	1.8 at 320W at 350 Ohms
	Urolog. Cutting 2:	2.6 at 320W at 800 Ohms
	Contact Coag. 1:	3.0 at 250W at 200 Ohms
	Contact Coag. 2:	4.8 at 150W at 500 Ohms
	Spray Coagulation:	4.4 at 100W at 1000 Ohms
	Bipolar Cutting 1:	1.8 at 80W at 500 Ohms
	Bipolar Cutting 2:	2.1 at 80W at 500 Ohms
	Bip. Coagulation:	1.8 at 80W at 100 Ohms
Output voltages:	Monop. Cutting 1:	max. 2100VPP, open circuit
	Monop. Cutting 2a:	max. 2700VPP, open circuit
	Monop. Cutting 2b:	max. 3300VPP, open circuit
	Urolog. Cutting 1:	max. 2100VPP, open circuit
	Urolog. Cutting 2:	max. 3800VPP, open circuit
	Contact Coag. 1:	max. 2000VPP, open circuit
	Contact Coag. 2:	max. 3100VPP, open circuit
	Spray Coagulation:	max. 4800VPP, open circuit
	Bipolar Cutting 1:	max. 800VPP, open circuit
	Bipolar Cutting 2:	max. 1100VPP, open circuit
	Bip. Coagulation:	max. 420VPP, open circuit
Protection class:	I	
Patient circuit:	CF defibrillation proof, monopolar and bipolar	
Operation mode:	INT 10s/30s	
Dimensions:	405mm X 135mm X 380mm	
weight:	13.6kg	
CE 0123	conform with 93/42/EEC	

1.5.6 Principle of Leakage Current Compensation

The terminals for active electrode and neutral electrode of an electrosurgery unit with CF type applied part are considered to be insulated from ground potential. Actually, due to the always present parasitic capacitances between inner wirings of the unit as well as electrode connection cables and ground, there is a weak electric connection where current can flow.This currents are designated as leakage currents. If an amperemeter is connected between one of the open terminals and ground, then this currents are measurable.

While the leakage currents caused by the mains voltage are in the range of a few Microamps, the leakage currents caused by the internal RF high voltage source may be in the range beyond 100 Milliamps. From this reason there are upper limits for leakage currents which are measurable from one of the electrode terminals to ground which shall not be exceeded.

To keep it within this limit, the RF leakage current of the ME 401 is monitored. On reaching the maximum permissible value the output voltage of the generator will be diminished until the leakage current is within the permitted range again.

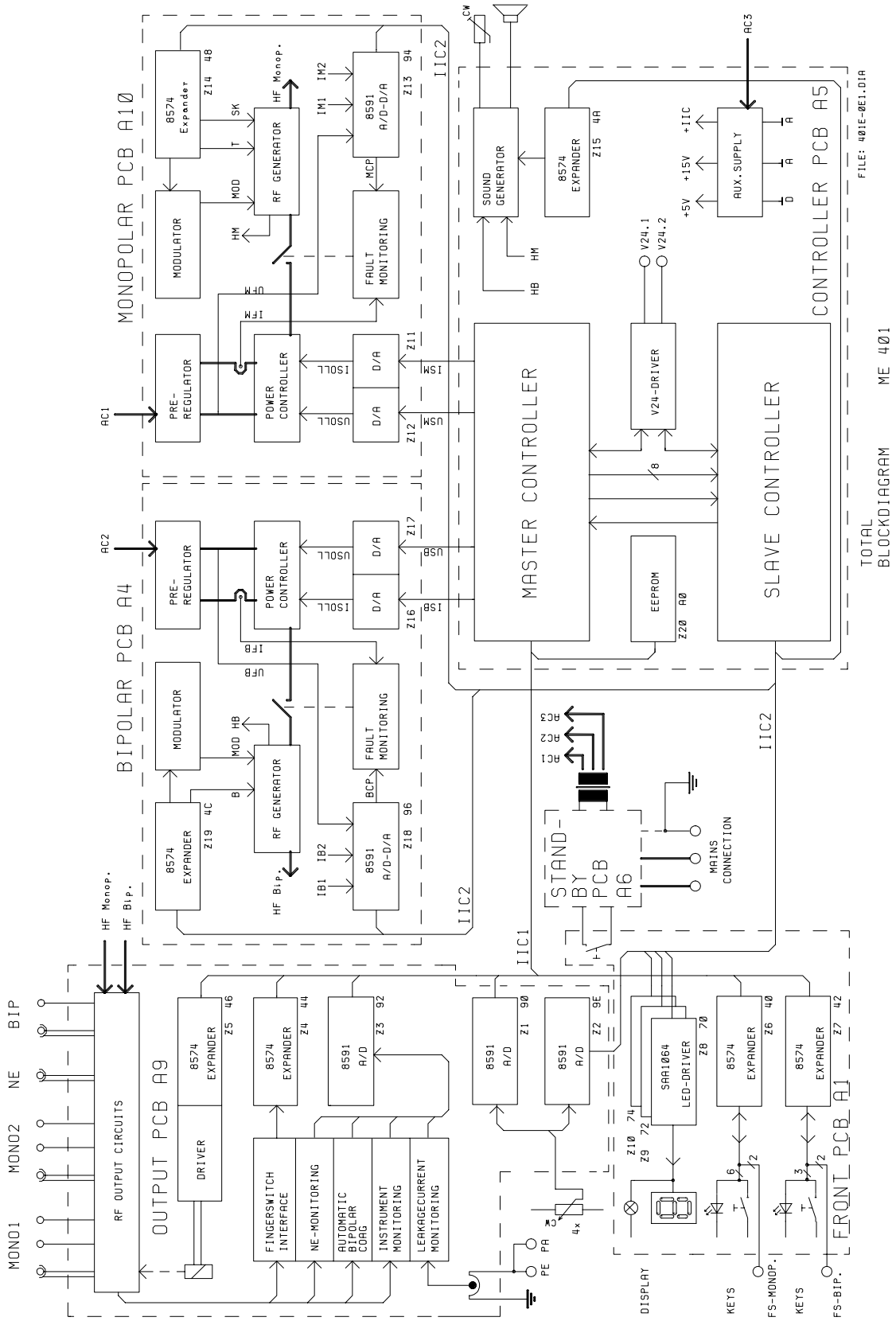
In surgical operation, the active electrode has no contact to ground and no considerable leakage current can be established from this terminal of the unit. The neutral electrode is in direct contact to the patient, but the patient is normally insulated from the grounded operating table by a cloth layer. Only the capactiance between patient and table permits a current flow. In case of wetting of the cloth layer which is not unusual in some procedures especially in urology, an unimpeded leakage current can form which activates the limiter function of the leakage current monitor. The reduction of output voltage associated with that may be negative for the surgical properties of the unit especially in urology where operation with relative high RF power is usual.

The ME 401 in the version 0908 generates an additional RF leakage current at the neutral electrode side which is directed counterwise to that parasitic current and results in an extinction of the major part of it. So the limiter function of the leakage current monitor becomes no more active if the patient gets contact to ground because the resulting leakage current is always within the maximum permissible value.

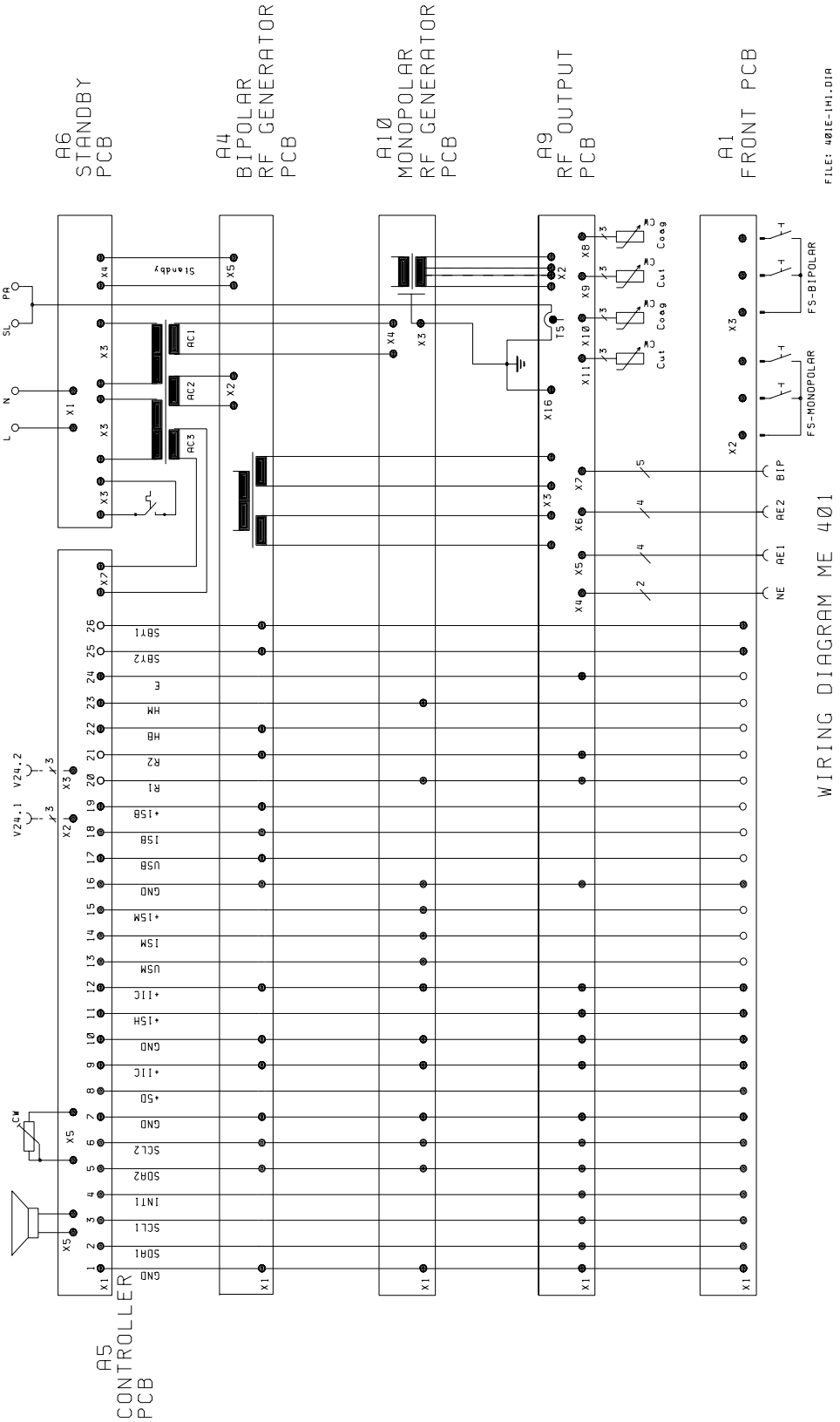
Due to conditions of physics, the reduction of the leakage current which is measurable at the NE terminal results in an increase of the leakage current measurable at the active electrode terminal. But in surgical practice this is no problem, since leakage currents from the active electrode side can only form poor. The fact that in case of direct ground contact of the active electrode the limiter function becomes active even at low power setting may give rise to wonder. But this is not a problem for surgical use.

By the way, this reduction of leakage currents from the neutral electrode side results in a decrease of noise generated by the electrosurgery unit and disturbing patient monitoring and video systems.

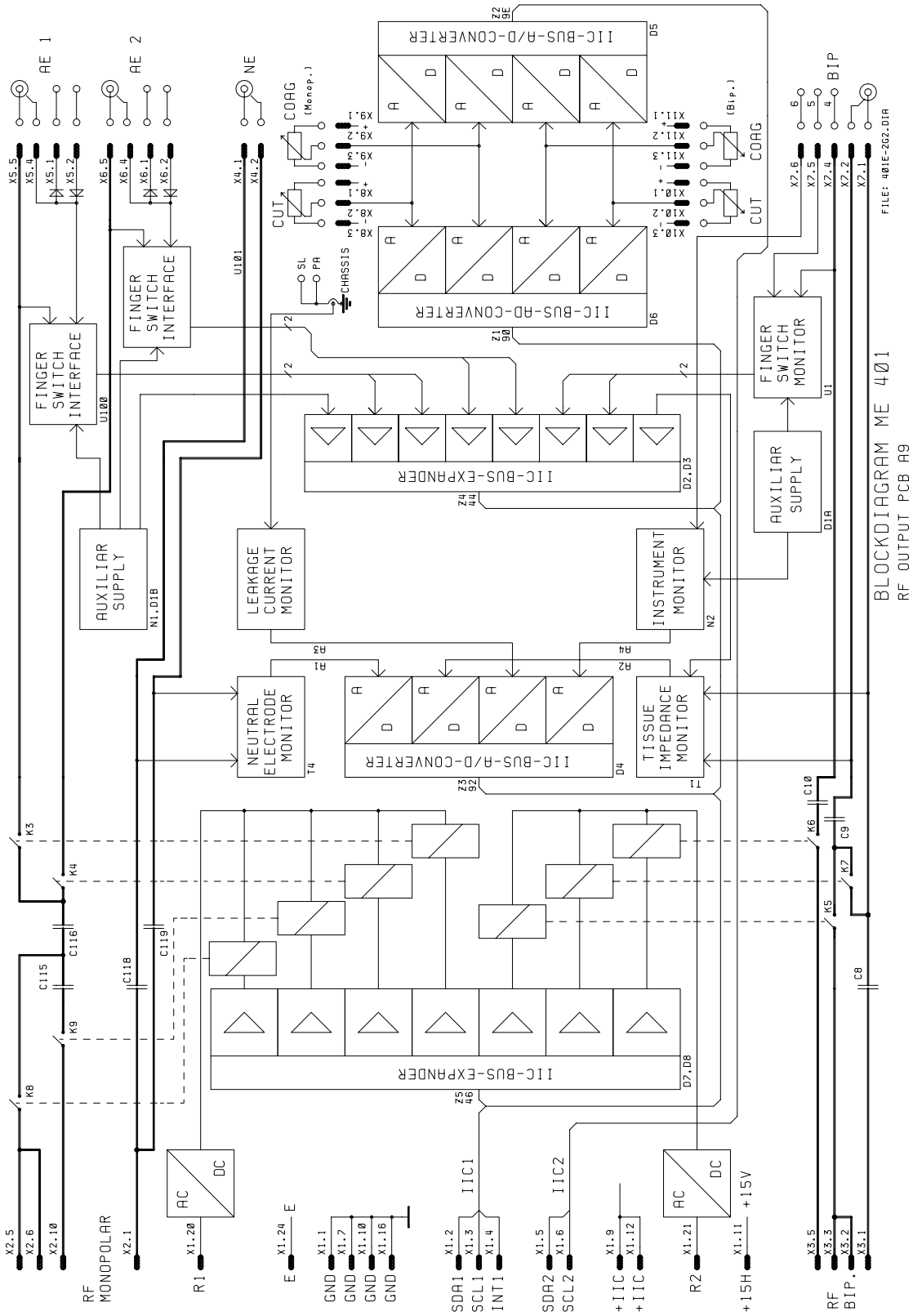
to 1.6.1 Block Diagram ME 401 Version 0908



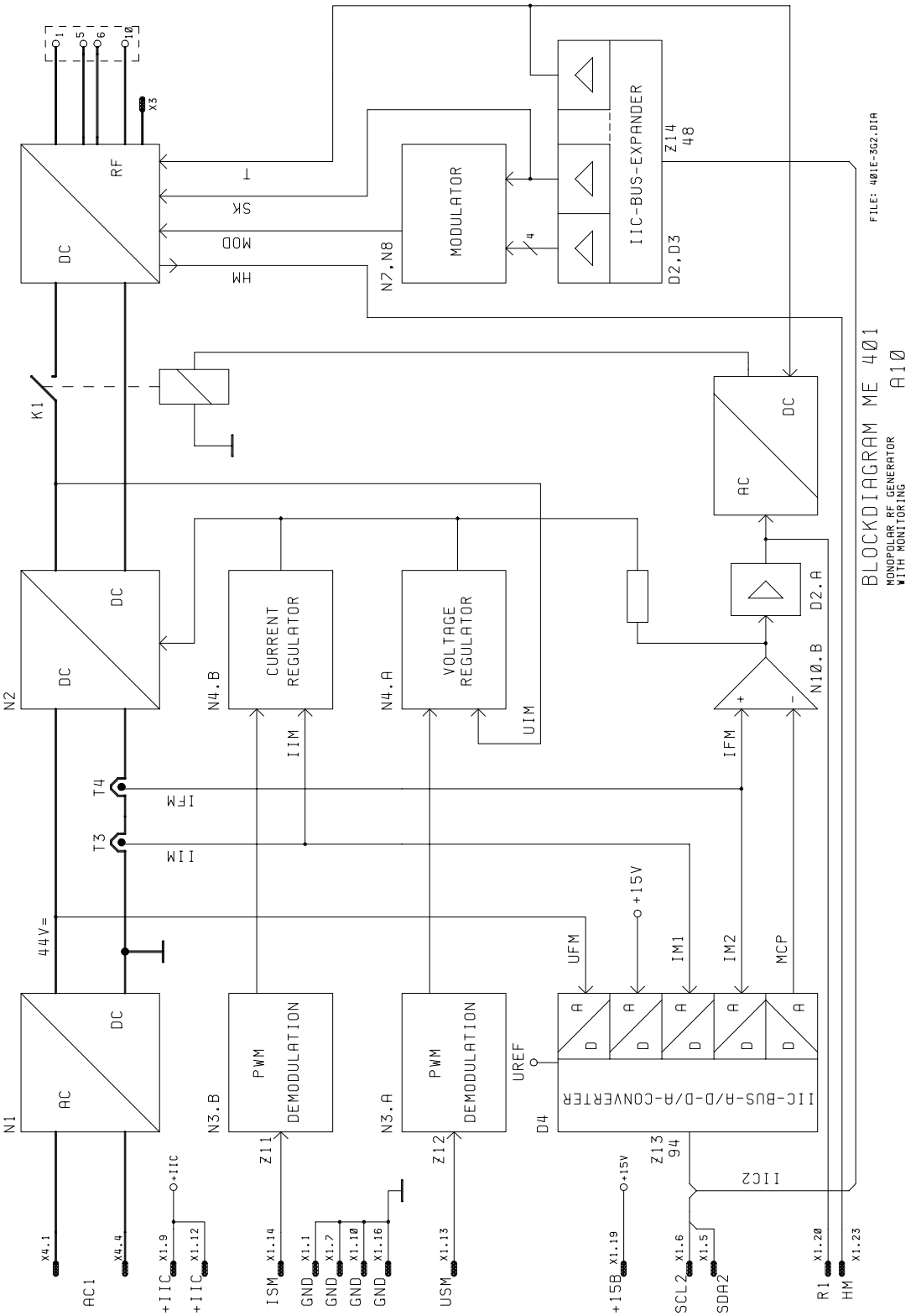
to 1.6.1 Wiring Diagram ME 401 Version 0908



to 1.6.3 Block Diagram RF Output PCB A9



to 1.6.4 Block Diagram Monopolar RF Generator A10



to 2.1 New Components for ME 401 Version 0908

Pos.	Designation	Ordering No.
51	RF output PCB A9 (for hardware 09)*	08-014-00-23
52	RF generator PCB A10 (for hardware 09)*	08-014-00-22
	Set of EPROMs with operation code 3.01M/S5.00 (SW 08)*	-
	Set of EPROMs with operation code 3.01M/S5.03 (SW 09)*	08-008-00-17

*) For detailed information, see item 5.

to 2.4 Disassembling and Reassembling of RF Output PCB A9 (51) for Hardware 09

1. Open unit according to 2.2.

2. Release countersunk screws (71) and remove top board holder (8).

3. Disconnect bus cable (40) from front PCB A1 (50) and RF output PCB A9 (51). Bend cable backwards.

4. Disconnect grounding cable from the RF transformer at the monopolar generator PCB and take it off of the gap in the rim of the output PCB. Release plug X2 of the monopolar output transformer at the left rear of the board. To perform this, lift plug off of the board surface by bending and pull simultaneous to the left.

5. Unplug cable connections X8 to X11 of the setpoint potentiometers at the top side of the board.

6. Unplug PE conductor cable (43a) from the case terminal (64) at the front left and pull it out of the current transformer at the RF output board. Unplug guarding conductor from terminal X16.

7. Lift board and release cable connections of RF sockets X4 to X7 as well as bipolar output cable connection X3 at the lower edge of the board. Remove board.

8. For reassembling, place board between the guiding pins at the side parts of the case base (bus connector at the left top) and rearrange cable connections X3 to X7 at the lower edge of the board. Then press board into the groove of the fixing bar. Take care of correct feed-through of the bipolar output cable and the PE conductor cable (43a).

Attention! Use only RF output PCB A9 (C 40-1512) for version 0908, differable at the gap in the edge at the upper left for cable feedthrough of the grounding conductor of the RF output transformer.

9. Feed PE conductor cable (43a) through the hole of the current transformer and connect it to the terminal (64) at the front left inside of the case. Connect guarding line to terminal X16.

10. Rearrange connection to the monopolar RF output transformer at the rear left of the board. Replace grounding conductor into the gap in the board edge and reconnect to terminal X3 at the RF output transformer at the monopolar RF generator PCB A10.

11. Rearrange bus cable connection at the RF output and front PCBs.

12. Rearrange cable connections X8 to X11of the setpoint potentiometers at the top side of the board.

13. Place top board holder (8) in handle cover (7) and tighten.

14. Perform alignments according to section 4.1.6.1.

15. Perform functional and safety check according to 4.1.2 to 4.1.5.

16. Close case according to 2.2.

to 2.5 Disassembling and Reassembling of Monopolar RF Generator PCB A10 (52) for Hardware 09

1. Open unit according to 2.2.

2. Release countersunk screws (71) and remove top board holder (8).

3. Disconnect bus cable from controller board A5 (54), bipolar RF generator board A4 (53) and monopolar RF generator board A10 (52). Bend cable to the front side.

4. Release grounding cable from terminal X3 at the RF output transformer. Release connector X2 of the output transformer at the left rear of the RF output board A9 (51). To perform this bend connector slightly off of the board surface and pull to the left simultaneous.

5. Release connector X2 from the mains transformer (23) and get connection cable out of the gap in the board.

6. Remove board unit topwards.

7. For reassembling place board unit between the guiding pins at the case walls with basic and reinforcement board and press into the groove of the fixing bar at the bottom. Take care of proper position of the PE line cable and the bipolar output cable in the gaps in the lower board edge.

Attention! For version 0908, use only monopolar RF generator PCB A10 (C 40-1513), differable at the RF output transformer with terminal X3.

8. Rearrange connection of the RF output transformer to the left rear of the RF output board A9 and grounding cable to terminal X3 at the RF output transformer.

9. Place the mains transformer cable in the keyhole shaped gap right in the upper edge and rearrange cable connection X4.

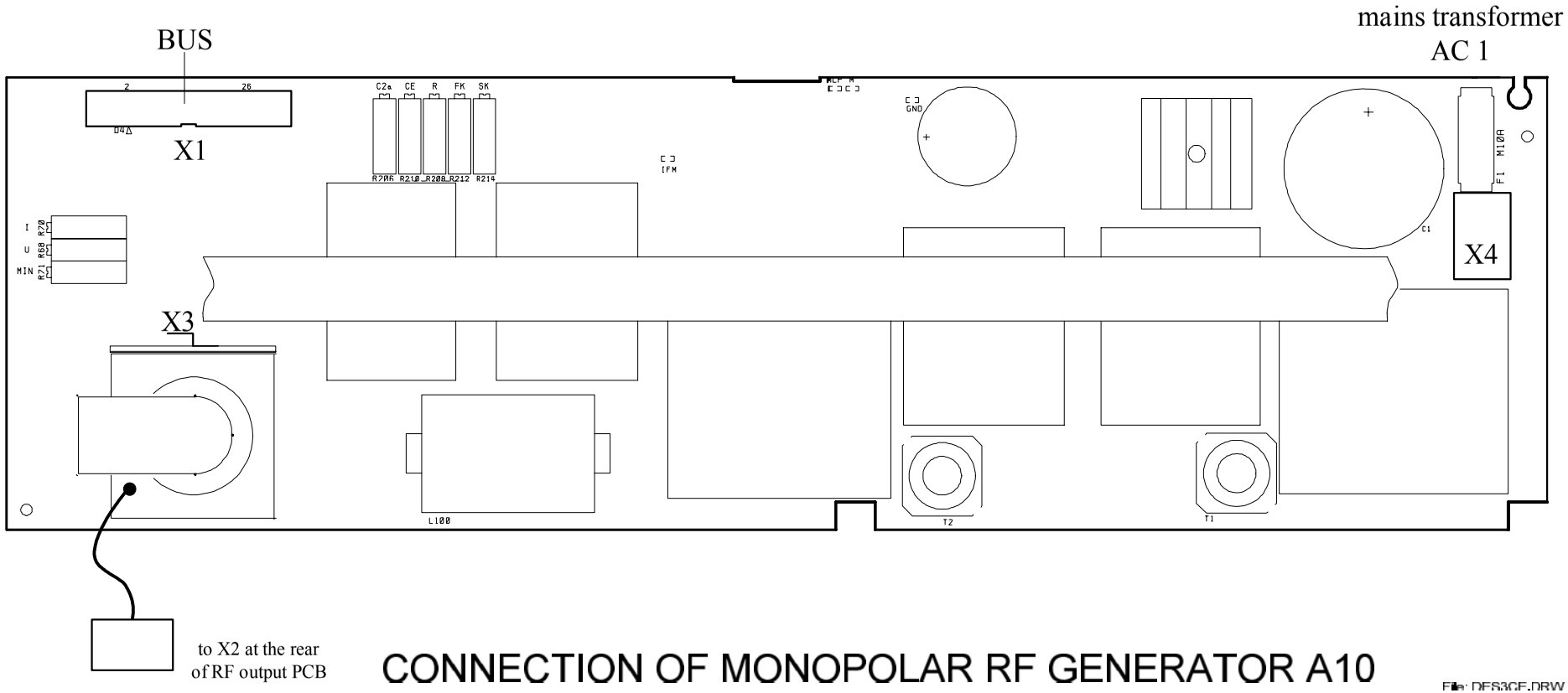
10. Rearrange bus cable connection to monopolar RF generator PCB A10, bipolar RF generator PCB A4 and controller PCB A5.

11. Place top board holder (8) and screw on.

12. Perform alignments according to 4.1.6.2. **Deviating from this, the adjustment of the degree of modulation for "Cut 2b" is to 4.5 Volts!**

13. Perform functional and safety checks according to 4.1.3 and 4.1.4.

14. Close case according to 2.2.



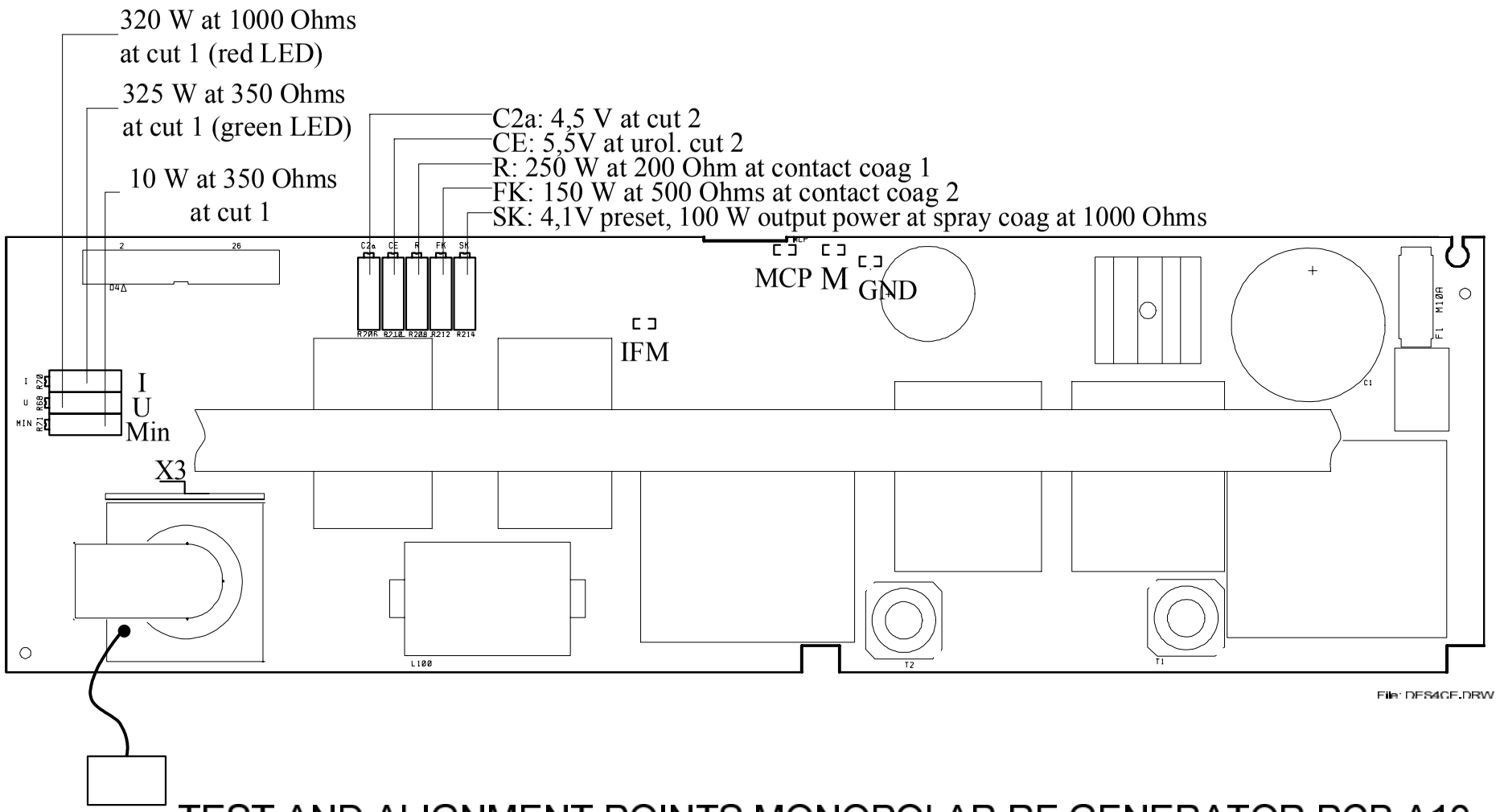
CONNECTION OF MONOPOLAR RF GENERATOR A10

File: DE53GE.DRW

4.1.6.2.3 Monopolar RF Generator PCB A10: Adjustment of Nominal Output Power

This item is valid for the adjustment of the output power of the monopolar RF generator board A10 which is assembled in the units with hardware state 09. For this, a new test procedure is valid. For setting of the degrees of modulation item 4.1.6.2 is valid with the exception that "Cut 2b" is to be set to **4.5 Volts** instead of 4.1 Volts as before.

- Set RF power meter to a load resistance of 100 Ohms.
- Set unit to "Cut 1", power setting to 320.
- On activation of monopolar cutting, adjust to an output power of 320 Watts with the trimmer "U" at the left side of the monopolar board (access through an orifice at the left side of the case). Note that the red LED at the monopolar board will light.
- If the green LED would light, turn trimmer "I" so far that the green LED turns to dark and the red LED will light.
- Set power meter to a resistance of 350 Ohms.
- On activation of monopolar cutting, adjust output power to 320 Watts (access through an orifice at the left side of the case) with the trimmer "I". Note that the green LED at the monopolar board will light.
- This previous check/adjustment is to repeat alternately until both adjustments are correct:
- Setting for "Monopolar Cutting" to 10, short before left end.
- On activation of monopolar cutting, adjust output power to 10 Watts (170 mA) with the trimmer "Min" (access through an orifice at the left side of the case, 10 Watts correspond to 170 mA at 350 Ohms).
- Set power to 160 and activate monopolar cutting.
- Compare actual value displayed by the power meter with test report sheet and check for compliance with tolerances.
- Set power meter to 1500 Ohms.
- Set power of the unit to 320.
- Activate monopolar cutting, compare displayed value with test report sheet and check for compliance with tolerances.
- Set unit to "Monopolar Cutting 2a" (select key for "Monopolar Cutting 2" and check the DIL switch 2 at the controller board for being set to off).
- Set power to 320.
- Set power meter to 350 Ohms.
- On activation of monopolar cutting, compare the value displayed by the power meter with the test report sheet and check for compliance with the tolerances.



TEST AND ALIGNMENT POINTS MONOPOLAR RF GENERATOR PCB A10

- Set unit to "Urologic Cutting 1".
- Set power to 320.
- Set power meter to 350 Ohms and activate monopolar cutting.
- Compare displayed value with test report sheet and check for compliance with tolerances.
- Set unit to "Urologic Cutting 2".
- Set power to 320.
- Set power meter to 800 Ohms and activate monopolar cutting.
- Compare displayed value with test report sheet and check for compliance with tolerances.
- Set unit to "Contact Coagulation 1" with power setting to 250, set power meter to 200 Ohms.
- On activation of monopolar coagulation, adjust output power to 250 Watts with trimmer "R".
- Set unit to "Contact Coagulation 2".
- Set power to 150.
- Set power meter to 500 Ohms
- Activate monopolar coagulation.
- Adjust output power to 150 Watts at 500 Ohms with trimmer "FK". Turn clockwise for more power, counterclockwise for less power.
- Select "Spray Coagulation" at the unit and set power to 100.
- Set power meter to 1000 Ohms.
- Activate monopolar coagulation and adjust output power to 100 Watts. Turn clockwise for more power, counterclockwise for less power.
- If the RF leakage monitor will become active, turn trimmer "IF" until 100 W can be adjusted.
- Check monopolar FR leakage currents according to 4.1.6.1 and adjust if required.

PRÜFPROTOKOLL TEST REPORT **- ME 401 -**

*QS*02*97**********

Serien-Nr.: ME401 0908 97 Netzspannung : **230 V**
Series-No. Mains voltage

1. Sichtkontrollen durchgeführt Name :_____
Visual inspections performed Name

2. Hochspannungsprüfung / Funktionsprüfung Name :_____
High voltage test / Functional test Name

3. Sicherheitsprüfung nach EN 60601
Saftey inspection according to EN 60601
Ausdruck des Prüfgerätes: Printout of the testing unit:

Space for IEC 601 safety tester printout

Meßergebnisse Position 3 i.O.: Name:
Measuring results position 3 o.k. Name

.....

4. Funktionsprüfungen: Functional tests

5. Ausgangsleistungen: Power outputs:
KK1 (250/250± 50W/ 200Ω)=_____W
KK2 (150/150± 30W/ 500Ω)=_____W

CUT1 (320/320± 64W/ 350Ω)=_____W SK(100/100± 20W/1000Ω)=_____W
CUT1 (320/190-270W/1500Ω)=_____W
CUT1 (160/128-192W/ 350Ω)=_____W BK(80/ 80± 16W/ 100Ω)=_____W

CUT2a(320/256-384W/ 350Ω)=_____W BC: [ ]symmetr 800Ω [ ]coaxial 500Ω
CUTU1(320/256-384W/ 350Ω)=_____W BC1(80/ 80± 16W)=_____W
CUTU2(320/256-384W/ 800Ω)=_____W BC2(80/ 64- 96W)=_____W

6. Netzstromaufnahme: (230V) [AV] Mains current consumption:
standby 230V (< 0,2 A)=_____A
CUT E (320/800Ω) (< 3,0 A)=_____A

7. HF-Ableitströme : (nach IEC 601-2 §19.102, SK: 100/200Ω)
HF-leakage currents (according to IEC 601-2 §19.102, SK: 100/200Ω)

Monopolar 1 (<100mA)=_____mA Bipolar (<80mA) =_____mA
Monopolar 2 (<100mA)=_____mA (BC2: 80/200Ω)
NE (<100mA)=_____mA

Prüfergebnisse Pos.4-7 i.O. Datum: Name:
Test results position 4-7 o.k. Date Name

.....

8. Dauertest (360 Schalt.;5/15Sek.;2Std.) Name:
Burn in test (360 cycles;5/15 sec.;2hrs.) Name

Sample of a test report sheet for units with hardware/software state 0908 (serial end no. 1051 to 1063)

5.4.10 Configuration 0908

This configuration differs from the configuration in a new not downwards compatible RF output PCB and a new not downwards compatible RF generator PCB. The new and altered properties are supported by a new not downwards compatible software.

Serial numbers:	ME 401 0908 97 1051 to ME 401 0908 97 1063
Software:	3.01M/S5.00 (SW 08)
Front PCB A1:	Version 02: Three monopolar coagulation keys, not interchangeable with version 00. As a spare part, also version 01 can be used.
RF output PCB A9:	Version 00. Not to be confused with RF output PCBs A2 or A7! As a spare part, also version 01 can be used.
Monopolar PCB A10:	Version 00. Not to be confused with monopolar RF PCBs A3 or A8! As a spare part, also versions 01 or 02 can be used.
Bipolar PCB A4:	Version 04. As a spare part, also version 05 can be used.
Controller PCB A5:	Version 01
Standby PCB A6:	Version 00

martin
Medizin-Technik

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